FURTHER INVESTIGATION OF LOOK-ALIKE DRUGS

HEARING

BEFORE THE

SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL HOUSE OF REPRESENTATIVES

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FURTHER INVESTIGATION OF LOOK-ALIKE DRUGS

THURSDAY, AUGUST 12, 1982

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL,
Washington, D.C.

The select committee met, pursuant to call, at 9:04 a.m., in room 2247, Rayburn House Office Building, Hon. Leo C. Zeferetti (chairman of the select committee) presiding.

Present: Representatives Leo C. Zeferetti, James H. Scheuer, Tom Railsback, Benjamin A. Gilman, Lawrence Coughlin, E. Clay Shaw, Jr., Michael G. Oxley, and Henry J. Hyde.

Staff present: Patrick L. Carpentier, chief counsel; Brenda L. Yager, minority counsel; George R. Gilbert, associate counsel; Sandra J. Boek, assistant minority counsel; and Elliott A. Brown, minority professional staff member.

Mr. ZEFERETTI. Good morning, ladies and gentlemen.

Today, the Select Committee on Narcotics Abuse and Control continues the inquiry we began last fall into the problem of look-alike drugs.

Look-alike drugs are capsules and tablets made to resemble commonly abused controlled substances such as amphetamines, barbiturates, and Quaaludes. Although these pills usually contain substances approved by the Food and Drug Administration for use in over-the-counter drugs such as cough and cold remedies and diet aids, look-alikes serve no legitimate medical purpose, but are merely intended to promote drug abuse. They exploit the recreational, nonmedical use of the controlled substances they mimic, and the unscrupulous manufacturers and distributors of these products proclaim them as the safe, legal way to get high. On the street, look-alikes are often represented and sold as actual controlled substances.

Prompted by constituent inquiries, mailed flyers and magazine advertisements for look-alike drugs, the committee held an initial hearing in New Jersey last October to examine this most recent drug abuse development. We found that the look-alike industry had mushroomed dramatically in the short space of 1 to 2 years and that the abuse of these products was widespread, especially among our youth. We also heard that, contrary to representations made about their safety, look-alikes were responsible for at least 11 deaths and countless other injuries and adverse drug reactions. The committee also heard testimony about efforts underway at that time at both the Federal and State levels to counter the growing

look-alike problem. These efforts included Federal seizures of look-alike drugs and manufacturing equipment, imposition of stop-mail orders against look-alike distributors, development of a model State law to prohibit the look-alike trade, enactment by some States of look-alike legislation, and State actions against look-alike dealers based on consumer protection and other grounds.

Since our hearings last fall, the select committee has continued to receive reports that the look-alike trade is flourishing. There is some evidence that look-alike promoters are altering their products to avoid State and Federal regulatory actions based on the similarity between look-alikes and controlled substances. For example, some manufacturers are now producing pills that no longer mimic the appearance of controlled substances, but still pose serious risks of health to users. There is also evidence that use of look-alike drugs and other over-the-counter stimulants by young people is increasing sharply.

In light of these circumstances, the select committee believes a review of the look-alike problem at this time is needed. The purposes of our hearing today are to examine recent changes in the look-alike trade and trends in the use of these drugs, and to determine how successful Federal and State efforts to control look-alikes have been and whether Federal agencies, recognizing the serious risk to public health these products present, are exercising their current authority to the fullest extent possible. We also want to explore whether existing Federal authorities are adequate to respond to this problem or if new Federal authority is needed to put an end to the manufacturing and marketing of these insidious products. Finally, we will hear about the steps being taken by one private pharmaceutical company to counter the look-alike trade.

Our witnesses today are Mr. Tyrone Fahner, attorney general of Illinois; Dr. William Pollin, Director of the National Institute on Drug Abuse; Dr. Sorell Schwartz, professor of pharmacology, Georgetown University School of Medicine and Dentistry; Mr. Charles Lents, counsel for regulatory affairs, Warner-Lambert Co.; and representatives from the Food and Drug Administration, the Drug Enforcenment Administration, the U.S. Postal Inspection Service and the Federal Trade Commission.

Before introducing our witnesses, I invite my colleagues on the committee to make opening statements.

Mr. RAILSBACK. Thank you, Mr. Chairman, and my remarks will be very brief. I want to thank you for scheduling and holding a hearing on look-alike drugs. Look-alike drugs are a mushrooming problem. Besides the potential for consumer fraud, they have served the purpose of introducing many young people to the drug culture.

There is evidence that look-alikes have caused strokes, and death to the users. And yet, all of the substances in these pills are legitimate over-the-counter drugs.

Control of the products is very difficult. States and their attorneys general are working to combat the problem. However, the existence of look-alike drugs persists and continues to grow.

Hopefully, this hearing can clarify what jurisdiction the Federal agencies currently have and what their roles should be in eradicating this nationwide problem.

I am aware, Mr. Chairman, that we have had earlier hearings. I want to applaud you for holding another hearing. I happen to think it is a most serious problem, and it is something that we can perhaps deal with from a Federal standpoint, and I am also delighted to have my attorney general, Tyrone Fahner who has been one of the leaders in this effort.

Mr. ZEFERETTI. Thank you.

Mr. Hyde?

Mr. HYDE. Thank you, Mr. Chairman. I just want to join both you and Tom Railsback in welcoming our distinguished panel of witnesses today on this important and troubling problem. I also want to sincerely commend you for the time and effort you and your superb staff have given to this very troubling problem.

The attention and the scholarship that has gone into the material you have prepared is superb and I cannot but think some good legislative results will emerge. I am gratified that Tyrone Fahner, the Attorney General of Illinois, who has done such an effective job in this and so many other areas is here this morning, and I am anxious to hear what he has to say.

Mr. ZEFERETTI. Thank you.

Mr. Fahner, would you please step up to the witness table, and Tom, I will give you the pleasure of introducing Mr. Fahner.

Mr. RAILSBACK. Thank you, Mr. Chairman, and members of the committee.

I would like to introduce a good friend, Tyrone Fahner, who has had a very distinguished career in law enforcement before he became attorney general in 1980.

He is a former Assistant to the U.S. attorney for the northern district of Illinois, and is the former director of the Illinois Department of Law Enforcement.

His legal career includes a master of law degree from Northwestern University, and private practice with one of the large firms in Chicago.

He is currently the chairman of the Midwest Conference of Attorneys General, and in October 1981, during the meeting of the National Association of Attorneys General, he chaired the Conference on Look-Alike Drugs.

The focus of the conference was what States could do to combat the problem. He has also met with Federal officials on the issue. As the attorney general, I happen to know from firsthand experience, he is aggressively pursuing the problem in Illinois.

He has initiated 40 successful cases under the Illinois Consumer Fraud and Deceptive Business Practices Act against look-alike manufacturers and distributors. Further, he supported and encouraged the recent passage of a look-alike law by the Illinois Legislature.

We are delighted to have you, and we look forward to hearing your remarks.

Mr. ZEFERETTI. Thank you, Mr. Railsback. I, too, join in that welcome, Mr. Fahner. We have your complete statement, and it will be made part of the record. You can continue in any manner you feel comfortable with, and we again welcome you to this committee.

TESTIMONY OF HON. TYRONE FAHNER, ATTORNEY GENERAL OF THE STATE OF ILLINOIS

Mr. FAHNER. Thank you, Mr. Chairman, Congressman Railsback, Congressman Hyde, members of the committee.

Thank you for allowing me the opportunity to testify before you today on this very serious topic, because the epidemic of look-alike drugs has swept our country almost uncontrolled.

We are faced with a serious drug problem in America that many of us didn't even know existed a few years ago. I would even venture to say that the growth of look-alike drugs has been the fastest-developing drug problem in the country, and very possibly, the most deadly.

We know of at least seven deaths in Illinois attributable to the use of look-alikes over the past year. And I say we know about seven, because in some parts of our State, including the city of Chicago, they don't keep records on drug overdose deaths that differentiate between death due to controlled and noncontrolled substances.

Credible authorities, however, suggest that well over a dozen young people have died in Illinois due to look-alikes in the past year.

Surprisingly, there have been more deaths linked to look-alikes than the real amphetamines in Illinois. We estimate that in 1981, 15 times more look-alikes were being manufactured in this country than amphetamines. Before June 1981, 1.7 billion doses of look-alikes were produced each year, and that means 8 look-alike tablets or capsules for every man, woman and child in America.

Those are frightening statistics, and they are even more so when you consider that these drugs are not prohibited currently by Federal law, and are still legal in many States.

They are manufactured without quality control, and they are being pushed on very young children as so-called safe, legal and effective stimulants.

How dangerous are look-alikes? One of the people we know to have died in Illinois due to look-alikes was a State fair worker, a young woman who died just about a year ago from this time. On August 4, 1981, she was working at the Illinois State Fair. She took a couple of look-alike tablets, and within an hour she was dead in the back lot of the fair.

Before that time, she was otherwise a healthy young woman with no known physical problems. Obviously, besides death, which is the biggest problem involved here, it is a common occurrence in our State, and I am sure around the country, to go into an emergency room, particularly on weekend nights, and find young people having their stomachs pumped or otherwise being treated for convulsions or some have had strokes as a result of the use or abuse of look-alike drugs.

Many people in law enforcement believed nothing could be done to restrict these drugs. I had been receiving for some time prior to April 1981 complaints from drug agents, local police, sheiffs, parents, and school administrators.

I was sympathetic, but without an apparent remedy, because no State or Federal criminal law applied. And there seemed to be very little that we could do in law enforcement with the problem.

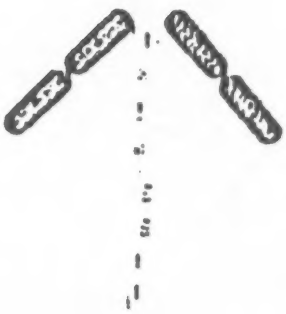
I was then given a copy of a pamphlet—I believe we have made it a part of the record—but in any event, a Xerox copy, if I could just hold it up, Why Pay More From a Non-Licensed Street Dealer? And inside, it would indicate with copies of the look-alikes and colors, Legal, very effective and profitable stimulants. For information, don't wait, call now, best prices in U.S. and Canada, and so forth.

Mr. ZEFERETTI Mr. Fahner, I would like to have a copy of that, and we will make it a part of the official record.

Mr. FAHNER. I will certainly do that. Thank you.

[The information follows:]

WHY PAY MORE FROM AN UNLICENSED STREET DEALER?



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Mr. FAHNER. But that particular pamphlet was being distributed on a school playground in Springfield, Ill., and, as I indicated, the pamphlet was literally pandering and appealing to the young people on a school playground.

You could buy these capsules, we found out, by the tens of thousands, and other companies offered free samples freely in Chicago, Springfield and throughout our State with only a phone call.

Any young person old enough to use a telephone could call and receive a bag, and we did so, to find out if this were true, of these look-alike tablets.

My staff and I decided we had to do something, so in May of 1981, we took our first action. We filed suit against the RSL Pharmacal Company of Maryland and three of its owners. That company is now out of business.

We sued civilly, Mr. Chairman, under the Consumer Fraud and Deceptive Business Practices Act of Illinois, the Illinois Deceptive Trade Practices Act, and the common law of nuisance. The theory of the nuisance count simply is that anything which causes danger to the health and well-being of the public is, in fact, a nuisance, and we brought three counts under those actions in each one of our lawsuits.

Now, over the past 18 months, the number of manufacturers and distributors we have sued has grown to 41 doing business either in Illinois or doing business into Illinois from 15 other States.

About two-thirds of the firms we have sued have voluntarily stopped doing business in Illinois or have folded up and moved elsewhere, and the look-alike manufacturers currently will tell you that the amount of, or the flow of drugs has dropped from about 30 million tablets and capsules a week, to about 5 million.

Even if those statistics are remotely true, however, we have no illusions about our success. Some companies we have sued and closed have popped up again under a different name and location.

And just because we stop look-alike distribution in Illinois doesn't mean we have solved the national problem. It is my judgment that until Congress acts by giving law enforcement authorities a strict, enforceable look-alike drug ban, many more young people will die, and a group of low-life merchants will continue to profit at the expense of our young people.

Many States have already taken up the challenge of stemming the look-alike drug problem. In Illinois, in this past session of our General Assembly, we have proposed and passed legislation that we are confident will effectively stop look-alikes in our State.

And that bill will be signed soon I am told, by Governor Thompson. Under that legislation, the manufacture, sale, distribution and advertising of look-alikes would be illegal. Violation would be a felony punishable by up to 5 years in prison and a $20,000 fine.

And our bill also prohibits possession of look-alikes, with the first violation being a petty offense, and the second a misdemeanor.

The legislation further gives law enforcement the important weapon of civil forfeiture to seize and confiscate look-alikes and the equipment used to manufacture look-alikes to prevent continued distribution.

Now, our legislation is very carefully drafted and has received the endorsement and support of both the pharmacists and the

pharmaceutical industries. We have built-in safeguards that make it clear we do not intend to ban placebos used by medical personnel or drugs in the marketplace that were designed prior to the manufacture of the controlled substance which they may resemble.

Further, Mr. Chairman, it is not our intention to regulate legitimate, over-the-counter drugs that are properly labelled and packaged, sold with specific use instruction and regulated by the FDA Over-the-Counter Drug Review Section.

Last year, I hosted a Conference of the National Association of Attorneys General in Chicago on this very topic. After a day-long discussion—by the way, there were 22 States represented at that Conference—after a day-long discussion of the nationwide problem of look-alike abuse, the Association went on record to do something about this look-alike problem.

Just a year later, over two dozen of those States have passed laws banning look-alikes. And many more are currently considering similar action. But the sad fact is that unless you and your colleagues in the Congress take on the look-alike dealers on the national level, we can only win skirmishes and not the war.

Look-alike manufacturers and distributors operate on a national scale, using the Federal Postal Service, the national delivery companies and a network of local salesmen, and despite action by the U.S. Drug Enforcement Administration and the Postal Service to restrict look-alikes.

These are only administrative measures currently available, which do not have the force or effect of Federal criminal legislation.

There are still some who question the need to ban look-alikes in spite of the startling impact they have on our youth. I think we cannot make any mistake about the kind of sickening profiteers we are dealing with.

The people—and I am saying this from my own law enforcement experience, Mr. Chairman, members of the committee—the people who peddle look-alikes are the same type of sleazy people who will try anything to promote the drug culture to our children just to make a buck.

They are very importantly and seriously creating an atmosphere of acceptance of the drug culture at a much younger age than ever before. And they are doing so at a great danger to the health and well-being of our young people.

In Illinois, various school boards began to take action on this particular problem. The Moline School Board, the Decatur School Board, and many others have been working with the drug enforcement authorities and school administrators to do something about this serious problem.

Perhaps the best, very short story that I could tell you that impacts, or shows the impact of look-alike drugs, is one that I found out about when I was visiting Rockford, Ill., a short time ago. I went to a drug rehabilitation center, Mr. Chairman, and talked to a young man who has participated in the center, who is 17 years old.

And I asked him if he had ever been involved in look-alikes, and he laughed and he said, Well, the reason I am here is because of look-alikes. When he was 15 years old, he began to sell look-alike

drugs. Eventually, his parents threw him out of his home because of the way that he was acting with respect to his parents.

He had got his own apartment; he had two cars, one new car, a motorcycle; he bought clothes and food and used his look-alike drug profits that he peddled at the various high schools in and around Rockford, to purchase other pills, controlled substances, and indeed some cocaine.

I asked him how he ended up at 17 in this particular rehabilitation center, which is not a voluntary situation, and he said that he woke up one morning with a policeman standing over him, and he told him he was either going to the rehabilitation center or he was going to go to jail—he could make the choice.

About 6 months later, he is doing very well, but he said that he, himself, and those in the look-alike trade had been selling these things to young children 9, 10, 11 years old in the grade schools.

He said it was a common practice and he could tell you the corner to go out to in Rockford or other places of our State to see this occurring.

With that background, Mr. Chairman, I am convinced that if we pass a Federal law with truly tough sanctions against anyone who would try to peddle this death to our young people, then we will take the profit out of this business and it will dry up.

I thank you, again, Mr. Chairman. I will be happy to answer any questions that you or your members may have of me.

[The prepared statement of Mr. Fahner appears on p. 68.]

Mr. ZEFERETTI. Thank you so very much for your expert testimony.

Mr. Fahner, what we see of recent vintage, anyway, is more and more States enacting legislation to combat the look-alike problem, although I might add that States are going different directions as far as how punitive they want to be as a result of what they are doing or whatever impact they might have.

If we were to pass Federal legislation, could you recommend the type of legislation that you feel would have the kind of teeth in it that could make an impact on the overall problem?

Mr. FAHNER. Yes, Mr. Chairman. In fact, what I would suggest to this committee is a piece of legislation that would model what we passed in Illinois, because we, in fact, came to this particular set of laws and sanctions after I came here and conversed with members of the DEA, the FDA, the Postal Service people, other law enforcement types, and we are trying to structure a model law in the Association of Attorneys General that will withstand any of the challenges that will invariably come up in the courts regarding constitutionality and so forth.

And the best thing that I could suggest to this committee, as it comes together after we have conferred with Federal and State law enforcement people, would be the very statute that we have in Illinois. It is modeled, once again, after Federal consultation and after other statutes in other States. And I think if we had uniformity at the State and Federal level, over time, it would make all of our jobs much easier.

Mr. ZEFERETTI. They have complained—and when I say they, I mean DEA and the rest of the Federal law enforcement sector—they say that this problem possibly doesn't need Federal legisla-

tion, but maybe some regulations within the Federal agencies of responsibility could pretty much do the job.

We are sort of in a dilemma to see which way we are going to go so we don't violate anybody's rights.

Mr. FAHNER. Mr. Chairman, I began my service as a prosecutor, an assistant U.S. attorney, and I used to prosecute a number of drug dealers. I worked very closely with the DEA and its earlier groups, BNDD and so forth. You have a gentleman that is going to testify later on today from DEA that will express their concerns. I discussed those concerns with this fellow and others when I was here. I think the Federal people feel that with their limited resources and all the hard-drug problems, they don't want to be burdened with the enforcement of the look-alike problem.

But the difficulties with that logic are at least twofold. Some of the Federal agents in Springfield first brought this problem to me, saying that, "Look, we can't do anything about this," and we spend a lot of time and investigative resources thinking we are going to investigate and prosecute the hard-drug dealers, and we go and make an arrest, and find out that, indeed, our information has been coming—they have been purchasing or selling look-alike drugs.

So they are not going to have to do anything other than have a good law which they can enforce selectively or refer the case to State authorities as we do on other levels of criminal law enforcement right now.

The other problem is, if this country is serious about the enforcement of our drug laws, and I believe we are by recent actions, where it is really starting to make some progress, we have to back up not only the source of the drugs and get to the source, but we have got to start and cut off where this whole drug culture begins.

And the biggest problem with look-alikes, beside the fact of death and illness, is that they are literally being peddled to kids that are 8 and 9 and 10 years old and up. And it gets to be an in thing for those kids to do before they can put their lives together and make an independent judgment as to what is right and wrong.

I think if the Federal law could be fashioned in such a way that the Federal and State people would—that is the reason why I would like to see a uniform type of law—have similar acts, constituting a violation of State and Federal law, we could pick our form, as we are doing in other areas.

I am working very closely with the Department of Justice right now in medicaid fraud investigations and prosecutions where certain violations would constitute a Federal mail fraud violation or, indeed, a theft by deception under Illinois law.

The same sort of logic would apply here, and the Federal DEA, Mr. Chairman, would not have to add agents or anything else to deal with this. It is simply an additional tool which we at the State level could use as well.

Mr. ZEFERETTI. Have you or your office received the kind of cooperation from the Federal agencies that could warrant this kind of a change? Have you got the input from those Federal agencies to get the kind of information, intelligence and the like so that you can work hand-in-hand?

Because they are pretty much subjected right now, because of budgetary constraints, to loss of manpower, loss of ability to respond in a lot of cases. And I was just curious as to whether or not you find in your office, that you have been getting that kind of response?

Mr. FAHNER. I can't, obviously, testify as to what it is on the national level, but in Illinois, in particular, whether we are talking about the central, northern, or southern part of our State, the cooperation has been extraordinary.

It is based, however, at least to some degree, on personal friendships. Some of the people—I used to prosecute their cases when I was assistant U.S. attorney—are now the agents in charge, and so forth. I could name the individuals and they are people who are personal friends.

The U.S. attorneys are former trial partners of mine and so forth. So we have a pretty good situation in Illinois, and I could only praise the Department of Justice and the DEA in terms of what they have done to assist us, and we, in turn, have come back and shared our resources——

Mr. ZEFERETTI. I was directing my question directly to the look-alike problem, I know as far as reacting and responding to the whole impact on drugs, and hardcore drug problem, I don't think there is any question their agency goes beyond—I was just interested in this particular problem.

Mr. FAHNER. With respect to that problem, as I indicated in my testimony, the problem was brought to my attention by DEA agents and State enforcement agents together in the Springfield office.

And they are not prosecuting them Federally, of course, and cannot. But they are bringing us, at the State level, information that enables us to make the cases.

So on this particular point, as well, we have extremely good cooperation in Illinois.

Mr. ZEFERETTI. One last question, you reported some seven deaths, I think it was, in your testimony, that you have been able to find out about, because it is difficult getting that kind of information.

How do you get that information? How do you make that judgment that it is a look-alike death?

Mr. FAHNER. Dr. John Spikes is the chief toxicologist for the State of Illinois, and when we began our inquiry into this area back in April 1981, we went through some of the downstate areas and found that the death by various believed drug-related causes went back to the coroners' inquests and medical reports, and found seven young people——

I believe they were all under the age of 22—that had died. We tied the deaths under the inquest to look-alike drugs, specifically. We did this to make the point to our legislature that we had to do something about the problem. We stopped the inquiry because of its time consumption, but we are absolutely confident at least twice that number of people have died.

Our chief toxicologist has determined this, Mr. Chairman.

Mr. ZEFERETTI. Thank you.

Mr. Railsback?

Mr. RAILSBACK. Thank you, Mr. Chairman.

What penalties were imposed as a result of the actions that you took against some of the look-alike drug manufacturers in Illinois? What were the results of those cases?

Mr. FAHNER. The majority of the cases involved a consent decree whereby the manufacturer-distributor would simply fold up and cease doing business by court order or agreement not to do business.

A couple did not. In those cases, we had to litigate. We had penalties imposed—I believe a $20,000 fine in one case, under the Consumer Fraud Act, and $10,000 in another.

Mr. RAILSBACK. What are the maximum penalties you are able to impose?

Mr. FAHNER. Well, before Governor Thompson signs this particular bill, civilly, the maximum would be $50,000 per count under the Consumer Fraud and Deceptive Trade Practices Act in Illinois.

As a practical matter, we have had a little difficulty getting the courts to really acknowledge the problem. They're into the swing of things now, if I can put it that way. But for a time, they couldn't understand, when they had to deal with hard narcotics, why we were concerned about look-alikes.

Mr. RAILSBACK. What will be the penalties under the new statute?

Mr. FAHNER. A $20,000 fine and a 5-year maximum prison sentence. It is a felony.

Mr. RAILSBACK. Has there been a shift from the look-alikes to the nonlook-alikes that contain the same combination of substances that can be very harmful? Are you aware of that trend?

Mr. FAHNER. I am aware of a start and of a shift that way. What they really do is try and stay one step ahead of the law enforcement authorities. The current thing now is, instead of look-alike drugs per se, there is something called look-alike cocaine. I am sure you have heard testimony about that, where they advertised in these same magazines and pamphlets that you can get look-alike cocaine and get the same sort of feeling.

But I am familiar with the trend now, since we are dealing with this, to move to another area.

Mr. RAILSBACK. Is there a gradation of offenses? I understand some of the look-alikes are moving from one location to another, popping up again. Is there a more serious penalty for the second offense?

Mr. FAHNER. In Illinois, not under our statute. There is, in terms of simple possession—I didn't want to be in a position where, similar to the problem enforcing the marihuana laws, police officers are spending their time busting young children for possession of these tablets.

We still wanted a chance to confiscate them, so we have a petty offense, first time for possession, simple possession by any person, which is an option; second time is a misdemeanor for simple possession.

But, no; the repeated offense being the latitude permitted under the $20,000 fine and up to 5 years' imprisonment penalty of our felony provision.

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Mr. RAILSBACK. During your conversations with the Federal people, did you have any occasion to consult with the Federal Trade Commission?

Mr. FAHNER. I did not. We had someone from the FDA come to our conference in Chicago, but as to the Federal Trade Commission, I did not.

Mr. RAILSBACK. Had you requested them to get involved at all or did that not occur to you?

Mr. FAHNER. No. It occurred to me, but I thought, in my own judgment, that at that period of time, there was uncertainty, and I believe there still is, as to what the role of the Federal Trade Commission is, and we simply thought that their involvement might be superfluous.

And we dealt with the FDA, the DEA, the Postal Service, primarily.

Mr. RAILSBACK. Let me just say as a member of the committee that I for one have been very disappointed at the lack of involvement by the FTC. I understand, Mr. Chairman, that we did invite them to appear and testify, and that they were not going to send a particularly high-level official, and they apparently have not acted on their staff's recommendation that they do get involved.

Mr. ZEFERETTI. Well, they have a—from what I was told last night—was that they have a very difficult time because of the five commissioner kind of structure within the agency to have any one person represent the views of the entire five-commission agency.

So, they will send a witness who will talk, but they will talk on experience that they have encountered themselves rather than on a personal level, but not represent the agency itself.

Mr. RAILSBACK. If I can, I just want to express my feelings on FTC actions, even though it is my administration. I have been generally supportive of that agency. I am very concerned that the FTC can get involved with funeral directors and get involved with used-car dealers, and yet, apparently has not been very involved in the look-alike drug problem.

I want to thank Mr. Fahner.

Mr. FAHNER. Thank you.

Mr. ZEFERETTI. Mr. Hyde?

Mr. HYDE. Thank you, Mr. Chairman.

Look-alike drugs are a part of the overall problem of the drug culture, which seems to pervade society. I would like to ask you whether you think society is serious enough about this problem?

I say that in the context of a movie that is circulating now, featuring those two great entertainers Cheech and Chong, the title of which I deliberately did not memorize. It glamorizes the drug culture, and it is also getting nice reviews in the major papers. Of the two major papers in Chicago, one gave it a very poor review, and one gave it a very good review.

"Poltergeist," one of the really popular movies, featured this average American couple retiring, each smoking a joint, as very amusing and very acceptable conduct.

You also have "Saturday Night Live," which glamorizes the drug culture and makes light of it. We are not serious, are we, really, about the evil, the pernicious evil that this is causing in so many lives nor are we getting angry about it as a society?

Mr. FAHNER. Congressman, your examples are superb ones to demonstrate your concern, but the bottom line on the whole thing is exemplified by the "Saturday Night Live" reruns. You can see how pathetic Belushi's life is in that context.

But that issue aside, I can tell you that in Illinois, as I perform my responsibilities, I have gotten the majority of my support from people, not just in the General Assembly in an election year or an Attorney General in an election year, but from the Illinois PTA; from the Illinois Federation of Women's Clubs; from a number of these school administrators who have asked me to come, and I have sent representatives to drug forums, educational forums around the State of Illinois, and there are a whole bunch of things.

They are dead serious about it, and they are concerned and they are worried, and maybe the best way to indicate that is—and you served in our general assembly in Illinois, and I don't know if there was ever a time when anything passed out of the Illinois House 171 to nothing out of 177 members, the other 6 weren't there to vote—but our look-alike drug legislation did. And it passed unanimously, with every member voting in the Senate, and they have gotten more mail from concerned people about this particular problem.

The same was true about our Narcotics Profit Forfeiture Act, part of our drug legislation package this last session.

So I think the real people, as I understand them to be, at least by my definition, are very concerned, very worried, and believe that the time is now to do something about it, while they still can.

Mr. HYDE. I hope so. I wish the opinion-molders and the movers and shakers of our society were equally concerned about it. In sports, we are seeing, it is much more pervasive than any of us imagined, and some of these sports figures are involved. I don't recall them being hauled before grand juries demanding to know who their suppliers are, nor their being sent to jail.

I do know they are being protected, and as long as they get into a rehabilitation program, everything is fine. Maybe that is the best way to handle that situation. But I am very pessimistic about our society as attitudes, even though there are some things we don't tolerate, in the political area, and in the religious area. Too few, but there are some.

Unfortunately, we have not reached a point where this glamorization of the drug culture is thought to be thoroughly revolting and is treated as such by the communications and entertainment industries.

I hope we don't have to go too far down the road to reach that point.

I thank you very much for your contribution to this important problem.

Mr. FAHNER. Thank you, Congressman. My only comment would be that the sports personnel that you talk about have been in Louisiana and Florida to my general knowledge, and I guarantee you that if any come to Illinois and have that, if we are capable of doing so, we will take them to a grand jury, if I have to use a Federal grand jury.

As I said, we have had good cooperation, and I am sure that wouldn't be a problem in our State. I guarantee you that.

Mr. HYDE. Thank you.

Mr. ZEFERETTI. Mr. Coughlin?

Mr. COUGHLIN. Thank you very much, Mr. Chairman.

We appreciate your taking your time to come here and present this testimony very much, Mr. Attorney General. In Pennsylvania, we do have a look-alike drug law, as you know. Our attorney general informs us that we haven't had sufficient experience with it to really be able to evaluate what we have, and one of the difficulties is defining a look-alike drug.

In your Illinois law, how do you define a look-alike drug?

Mr. FAHNER. Mr. Coughlin, first, let me say that General Zimmerman, who is doing a superb job in your State, and participated in our conference, tells me that at least, relatively, in the short-term future, it is hopeful that you will have a look-alike provision in your State.

But, if I may, because we were very careful to define look-alike in a way that would meet the tests of constitutionality and everything else, it literally goes on for about three pages, I think if I could simply make a copy of the definition as part of the record, unless you want me to read it into the record, that might be most helpful.

Mr. COUGHLIN. If you could do that.

Mr. FAHNER. I would be happy to do that.

[The information follows:]

An act to amend Sections 102, 401, 402, 404, 407, 410 and 505 of and to repeal Section 403 of the "Illinois Controlled Substances Act", approved August 16, 1971, as amended.

Whereas, The General Assembly recognizes the special dangers and unique threat to the public health, safety and welfare posed by look-alike substances, including:

(1) that their particular appeal to and widespread marketing among young people promotes acceptance of drug abuse;

(2) that their misrepresentation as to ingredients and effects leads to unanticipated reactions and confusion as to the effects and dosage levels of actual controlled substances;

(3) that the wide availability of constituent ingredients results in great ease of their manufacture and generates immense profits for manufacturers and distributors; and

(4) that their actual ingredients, though varied, create additional serious health hazards when the manner of administration or ingestion parallels that usually associated with the substances being imitated; and

Whereas, The General Assembly therefore intends by this Act to penalize the manufacture, delivery, possession with intent to manufacture or distribute, advertising and possession of look-alike substances in a manner commensurate with their distinct harm, which is in fact greater than that of many actual controlled substances; therefore;

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

SECTION 1. Sections 102, 401, 402, 404, 407, 410 and 505 of the "Illinois Controlled Substances Act", approved August 16, 1971, as amended, are amended to read as follows:

* * * * * * *

(z) "Look-alike substance" means a substance, other than a controlled substance or a drug for which a prescription is required under federal or State law, which (1) by overall dosage unit appearance, including shape, color, size, markings or lack thereof, taste, consistency, or any other identifying physical characteristic of the substance, would lead a reasonable person to believe that the substance is a controlled substance, or (2) is expressly or impliedly represented to be a controlled substance or is distributed under circumstances which would lead a reasonable person to believe that the substance is a controlled substance. For the purpose of determining whether the representations made or the circumstances of

the distribution would lead a reasonable person to believe the substance to be a controlled substance under this clause (2) of subsection (z), the court or other authority may consider the following factors in addition to any other factor that may be relevant:

(a) Statements made by the owner or person in control of the substance concerning its nature, use or effect;

(b) Statements made to the buyer or recipient that the substance may be resold for profit;

(c) Whether the substance is packaged in a manner normally used for the illegal distribution of controlled substances;

(e) Whether the distribution or attempted distribution included an exchange of or demand for money or other property as consideration, and whether the amount of the consideration was substantially greater than the reasonable retail market value of the substance.

Clause (1) of this subsection (z) shall not apply to a noncontrolled substance in its finished dosage form that was initially introduced into commerce prior to the initial introduction into commerce of a controlled substance in its finished dosage form which it may substantially resemble.

* * * * * * *

SEC. 404. *(a) For the purposes of this Section:*

(1) "Advertise" means the attempt, by publication, dissemination, solicitation or circulation, to induce directly or indirectly any person to acquire, or enter into an obligation to acquire, any substance within the scope of this Section.

(2) "Distribute" has the meaning ascribed to it in subsection (s) of Section 102 of this Act but as relates to look-alike substances.

(3) "Manufacture" means the producing, preparing, compounding, processing, encapsulating, packaging, repackaging, labeling or relabeling of a look-alike substance.

(b) It is unlawful for any person knowingly to manufacture, distribute, advertise, or possess with intent to manufacture or distribute a look-alike substance. Any person who violates this subsection (b) shall be guilty of a Class 3 felony, the fine for which shall not exceed $20,000.

(c) It is unlawful for any person knowingly to possess a look-alike substance. Any person who violates this subsection (c) is guilty of a petty offense. Any person convicted of a subsequent offense under this subsection (c) shall be guilty of a Class C misdemeanor.

(d) In any prosecution brought under this Section, it is not a defense to a violation of this Section that the defendant believed the look-alike substance actually to be a controlled substance.

(e) Nothing in this Section applies to:

(1) The manufacture, processing, packaging, distribution or sale of noncontrolled substances to licensed medical practitioners for use as placebos in professional practice or research.

(2) Persons acting in the course and legitimate scope of their employment as law enforcement officers.

(3) The retention of production samples of noncontrolled substances produced prior to the effective date of this amendatory Act of 1982, where such samples are required by federal law.

SEC. 407. Any person 18 years of age or over who violates any subsection of Section 401 *or subsection (b) of Section 404* by delivering a controlled, *counterfeit or look-alike* substance to a person under 18 years of age who is at least two years his junior may be sentenced to imprisonment for a term up to twice the maximum term *and fined an amount up to twice that amount* otherwise authorized by the pertinent subsection of Section 401 *and subsection (b) of Section 404.*

* * * * * * *

Mr. COUGHLIN. It has to be based upon some kind of a deceptive representation?

Mr. FAHNER. In concept, let me just say that a look-alike is something which has no medicinal or personal value whatsoever, but its sole purpose is to make profit, and it is made by its designer-constructor to look like a controlled substance, which would be illegal to purchase on the street in every case, except by prescription, over the counter.

And a better example is the pamphlet which I passed up, which you made part of the record. If the trademark of a legitimate—that is, a legally-made controlled substance would be to have a trademark "M" on the side in a horizontal fashion, they would take the "M" and make it in a vertical fashion, so that you almost have to be—you do have to be a doctor or a pharmacist to know, at least by appearance, the difference. And of course, you have to be a chemist to tell the actual difference.

And one of the problems we have had is the strength of these look-alikes. We had a case where a young woman died in a hospital emergency room. Her mother brought her in, she was convulsing.

The doctor in the emergency room took a couple of pills out of her levi pockets, and found, he thought quickly, that she had been taking amphetamines. He treated her accordingly, which was the wrong treatment given her particular problems.

So, even an educated medical person has difficulty telling the difference. That is the entire essence. They are simply caffeine-based pills with phenylpropanolamine, and some other antihistamines. And there is no quality control, so they could be anything, but the whole idea is they are for profit, and they are made to look like something they are not.

Mr. COUGHLIN. You suggest in your testimony some kind of Federal legislation in this area. Are you talking about a Federal law? Historically, this kind of law has been a State proposition, except for FTC authority.

Mr. FAHNER. Mr. Coughlin, I am talking about a Federal law modeled after the Illinois law, which, as I mentioned earlier, was patterned after discussion with the Federal people. The reason we need it is because in Illinois, when we closed up, we had five people that were manufacturing in Illinois and distributing; we had another dozen or so that were manufacturing out of Illinois and distributing into Illinois.

The problem is when we put our five dealers out of business, they literally sold their stock, or took their stock, to Iowa, in two instances; one to Tennessee. I am not sure about the rest. They changed their name, and started again in another State, mailing the stuff into our State.

So that effectively, you have to track these people through the various things. As long as there is one State that they can operate out of, and use the mails or use the private postal services, the United Parcel, whatever it may be, we are going to have a problem in this country.

And that is why we have to have Federal legislation. But as I indicated to the chairman previously, if it could be put on a Federal level, then we could enforce it at the State level.

In other words, we could go back and forth in terms of our enforcement responsibilities; it would not require, at all, additional Federal manpower or any other such thing, in my judgment.

It would simply be an additional tool for them to make arrests, indeed, defer cases, because the violation of a Federal law would also be a violation of our own laws in almost every instance.

And if our legislation would be more or less uniform, it would be very, very simple for us at the State level to enforce, in effect, the Federal laws.

Mr. COUGHLIN. Thank you, Mr. Chairman.

Mr. ZEFERETTI. Thank you.

And I can attest to some of the problems. We passed a law in New York—which I would like to have in this record—and now they are next door, into New Jersey, and making their distribution from that point, so I think we need some kind of regulatory Federal act.

[The law referred to appears on p. 103.]

Mr. ZEFERETTI. Mr. Gilman?

Mr. GILMAN. Thank you, Mr. Chairman.

First of all, I would like to commend the Attorney General for focusing attention on the look-alike problem, and for the good work that they have done in his State. I am pleased to report that New York State has now adopted a similar look-alike law. The Governor signed it into law in July.

How many other States now have look-alike statutes?

Mr. FAHNER. We just had our National Association of Attorneys General meeting a couple of weeks ago, and Attorney General Abrams told me that New York would have their law.

I think, as of our count there, there are 22 or 24 that now have look-alike laws. They are pending in approximately another dozen States, or at least are in the hopper somewhere. The remainder are nowhere right now.

Mr. GILMAN. Have you taken the proposal for having some Federal statutes up with the Federal law enforcement officials or with the Justice Department?

Mr. FAHNER. I took them up about 1 year ago, informally, to find out what their feelings would be, and as I indicated a little earlier, I believe that their feelings are that they don't need additional responsibilities. They have limited manpower to do what they have to do currently. And that is the reason why, without trying to make it a Federal problem, because it is not. It is a State problem.

I just think it would be better if we had Federal legislation to complement our State legislation so that we could enforce the laws together with our manpower and their laws in many instances.

But right now, I believe the current thought is that it is something that they ought not to be into, because of their resource limitation.

Mr. GILMAN. Who did you review that issue with?

Mr. FAHNER. I first met very informally with three gentlemen from the DEA. One of the gentlemen was Gene Haislip who will be testifying later at this hearing. I reviewed the issue with him before he was formally in office. In the casual conversation there was simply an acknowledgement that DEA currently deals with hard drugs and they didn't know if they really wanted to get into the look-alike drugs area.

I have not made any formal request that they do anything, per se, thinking that this was the appropriate body to make that initiative, because I have been in government, State and Federal, long enough to know that is the way to do things.

If you go to the agencies—quite candidly, I think the DEA will suggest that maybe the FDA do more. The FDA will say that their hands are tied, and the Postal Service will say they can only work with the mails.

And that isn't intended to be critical of any of those groups. I mean that sincerely. But I think that the movement will have to come from the Congress.

Mr. GILMAN. Would your major thrust, by way of Federal legislation, be concerned with false advertising and deceptive mail practices?

Mr. FAHNER. While these are areas that would affect all distributors, our major thrust would be to stop the manufacturer-distributor of these drugs. One of the problems that we have been trying to deal with in the various State legislation is the manufacturer's advertisements. But as you are aware there are first amendment considerations and prior restraint, in the limitation of advertising.

I think what you have to do is to make the look-alike trade illegal. Currently the profit margin is too good. If you can sell a pill that costs less than a penny to make for up to $2 in the street to young children, and there is no risk of criminal prosecution, the profit is great.

Once it is illegal, the critics of this legislation in my State have said, "Well, all you are going to do is drive it underground." Well, that is not true in this case, because the profit margin, although great, is not worth it if you can also go to jail, and not simply have to pay a fine.

So, I think the emphasis has to be on taking the drugs off the streets, and you do that by taking the legality away from these drug profiteers, and that will take care of this problem, at least 90 percent of the way.

Mr. GILMAN. Then you are suggesting a Federal statute modeled after the State statute which would just make the manufacture and distribution of look-alike drugs illegal?

Mr. FAHNER. That is correct. Once again, we do have a provision which goes to the advertising concept. It makes it illegal not for a magazine to receive the advertisement, but rather for the person who is manufacturing, selling, or distributing to advertise.

We put the onus on that person, not on the magazine or the newspaper. Then you stay away from the problems of freedom of the press and so forth.

Mr. GILMAN. What sort of a penalty do you impose in the Illinois statute?

Mr. FAHNER. It will be up to a 5-year sentence and/or a $20,000 fine.

Mr. GILMAN. Do you find that that is a severe enough penalty?

Mr. FAHNER. Well, we are hoping that it will be. The bill will be signed by our Governor, I am told, soon, and we anticipate that it will be. It is certainly in line with, and just a shade under those provisions for the hard narcotics.

And the reason we did that was to make sure that we didn't have a more stringent penalty for a previously noncontrolled substance than for a narcotic drug, or a controlled substance. But it is a pretty good penalty, and I think if we use it firmly and swiftly in our State, it will take care of the look-alike drug problem very quickly.

Mr. GILMAN. And has the statute been tested in court with regard to its constitutionality?

Mr. FAHNER. Our statute has not been, because it isn't signed. A Florida statute was tested, and was found to be unconstitutional, because Florida tried to do away with the intent feature of the criminal law, which you cannot do. That is what you learn in law school. I think they are going to correct that, and go back and revise it.

But we have watched the cases, and we have watched the statutes that have been around for a year or two, in Maryland in particular; Delaware, I believe. And we have drawn ours very carefully with a lot of research and anticipating all the constitutional challenges which were also brought up in the drug paraphernalia legislation.

So I am 99 percent confident that ours will withstand any challenge of any kind.

Mr. GILMAN. Thank you.

Thank you, Mr. Chairman.

Mr. ZEFERETTI. Mr. Oxley?

Mr. OXLEY. Thank you, Mr. Chairman.

Mr. Fahner, before your statute was passed, you proceeded in a civil nature after these various individuals and companies, and apparently were quite successful.

My question is, do you think the civil proceeding will be more effective with the present statute? As I understand it, it was just recently passed, and do you have any experience under that?

Mr. FAHNER. Well, we did sue 41 look-alike drug manufacturers, and largely with success. Some we are still litigating; a small number. With the rest, we have either been successful in closing them, getting fines, or simply putting them out of business.

The problem with that is, it solves our problem temporarily in Illinois, after suing 41 firms. As I indicated previously, they just go to another State, adjoining State, and then try and mail back into the State with a new name, a new marketing technique.

When we got the postal people to crack down, they went to United Parcel Service, and so forth. And the only permanent, or anything in the nature of a permanent solution to the look-alike drug problem, in my judgment, will be a Federal criminal sanction to be coordinated with our State sanctions, which will take the profitability, because, once again, the fear of jail plus losing the dollars will make a difference.

The profit is great, but it is nowhere near what it is with cocaine or heroin. So, our success has been very limited in the real sense. We can talk about it in Illinois, but we have just moved the problem to another State, and then they can deal back in one way or another.

Mr. OXLEY. It has been my experience that Federal prosecutors have been quite successful in many different types of cases, prosecuting under mail fraud. Many cases, somewhat questionable in terms of the hook that they use to bring it under mail fraud, but indeed they were quite successful.

Don't you think that under the present mail fraud statutes, the Feds could successfully prosecute these people?

Mr. FAHNER. No; I don't, because the method of packaging for the majority of these people is simply that they are safe, legal and

effective stimulants. Indeed, they are stimulants, and currently, in most States, more than half, they are still legal.

And I can say that I was one of the prosecutors in the early seventies that used the mail fraud statute in Illinois in a way that was thought to be reaching or constructive, depending on what your viewpoint was, but I couldn't reasonably fashion the use of the mail fraud statute in this case.

Mr. OXLEY. Has that not been done, then, at all?

Mr. FAHNER. To my knowledge, it has not been done. And there is still the problem, of course, of Federal prosecutors' priorities. They are not going to prosecute individuals, unless they can get the DEA or FBI to investigate.

The one thing that the Feds have done, they worked with the FDA to go in and use the FDA regulations to close up nine manufacturers and seize their manufacturing machinery, the things that put them together. But that was a one-shot effort about a year ago. And it is not going to do it.

Mr. OXLEY. With regard to the recent statute that passed in Illinois, is Illinois a determinant sentencing State?

Mr. FAHNER. Yes; it is.

Mr. OXLEY. And did the particular legislation that passed fall under the aegis of the determinant sentencing? Are we talking about 5 actual years now?

Mr. FAHNER. No; we are talking about up to 5 years, and we are—to what your understanding is, determinant sentencing, I think you are referring to our class X legislation, with a minimum mandatory.

Under this particular provision, it would be up to 5 years' imprisonment, and up to and/or $20,000 fine. There would not be a mandatory minimum penalty. It still would be probationable.

Mr. OXLEY. So, it would not be under the determinant sentencing, then?

Mr. FAHNER. Well, that is right. By your definition, it would not be.

Mr. OXLEY. Thank you.

Thank you, Mr. Chairman.

Mr. ZEFERETTI. Thank you, Mr. Fahner. I just want to say, I really appreciate your taking the time to come in from what I know is a busy schedule that you have back in Illinois. I want to thank you, also, for helping us make our case. As Mr. Hyde had said earlier, it is a very, very difficult task for us to bring to the public's awareness all the problems of drugs in our society, and we need that kind of evidence, we need that kind of experience, we need that kind of cooperation that lends itself, for us, to go hand-in-hand with the executive and legislative branch on the Federal side to get the priority, if you would, to make those very same agencies and those very same laws effective by giving it the kind of priority and attention it needs.

So on behalf of the committee, I want to express my sincere thanks.

Mr. FAHNER. Mr. Chairman, thank you very much for the opportunity to be here. Thank you, thank you very much.

Mr. ZEFERETTI. Our next witness will be Dr. William Pollin, director of the National Institute on Drug Abuse.

Good morning, Dr. Pollin. It is good to see you again. We welcome you before the committee. We have your complete statement, which will be made part of the record. You can proceed in any fashion you feel comfortable with.

TESTIMONY OF WILLIAM POLLIN, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

Dr. POLLIN. Fine. Thank you very much, Mr. Chairman. And I thank you for the invitation to address this important issue of the use of look-alike drugs in our country, especially among our youth.

This hearing provides an opportunity to publicize NIDA's concern about this emerging drug abuse phenomenon. I have submitted the complete statement for the record, and will abbreviate it in presenting this to you.

Mr. ZEFERETTI. Thank you.

Dr. POLLIN. We at NIDA are specifically concerned about two major categories of drugs that have become widely available to a growing extent over the last 2 years. First, true look-alikes, the drugs you have been hearing a discussion of up to now, and second, over-the-counter stimulants and depressants.

True look-alikes are products that mimic in size, color, shape, or marking, prescription stimulants and depressants. Look-alikes generally contains one or more of three nonprescription stimulants: Caffeine, phenylpropanolamine, ephedrine. Look-alike downers usually contain only antihistamines.

Overlapping with look-alikes are the rapidly growing group of over-the-counter stimulants and depressants which do not require prescriptions. Most of these psychoactive substances are marketed as diet aids, pep pills or sleep aids.

They are not manufactured to deceive the public and they do not look like controlled substances. However, they usually consist of the same ingredients as do the look-alikes: Phenylpropanolamine, caffeine and occasionally ephedrine, in various combinations.

We believe that both of these categories of products may contribute significantly to the national drug problem, particularly by young people. As you have heard, manufacturers of look-alike drugs frequently promote their products through college newspapers, handbills at truckstops, unsolicited literature from mail order firms, or through storefront operations often located near high school or college campuses.

The distributors promote the drugs as "100-percent legal" or "legal stimulants," and, they are often advertised by the common street names for amphetamines and barbiturates, such as "black beauties" or "yellowjackets."

The second category that I have referred to, over-the-counter psychoactive drugs, has shown a recent substantial spurt in number and use.

In 1979, an FDA panel of experts concluded that phenylpropanolamine was an effective appetite suppressant. Since the adoption of their report, there has been a sharp increase in the number and brands of diet and energy pills being marketed. Though these are legal stimulant drugs, they are readily abusable.

We are concerned about the possible relationship of this newly prominent group of easily available and heavily marketed legal psychoactive drugs to older, long-established patterns of drug abuse.

We believe that significant numbers of individuals may be using these substances for recreational, "legal highs." Such use can, in turn, act as a stepping stone to the use of other drugs, or contribute to making the drug experience an increasingly important or central part of an individual's life.

The advent of such "legal," recreational drugs, other than alcohol, is a relatively new phenomenon. It is still poorly defined, and the available empiric data as to incidence and prevalance are less firm than for other drugs or drug categories.

What data we do have, however, strongly suggest a significant increase in recent use. This may well be the most rapidly increasing drug area in terms of use levels. Such a trend is particularly noteworthy and disturbing when most other drug use among our teenagers appears to be on the downturn.

Perhaps the most relevant data come from the NIDA High School Seniors Survey. Although the data are indirect and inferential, this survey indicates that of the 16 classes of drugs monitored, only stimulant use showed a statistically significant increase in the last year.

Stimulant use is also of considerable importance since this is the most widely used class of illicit drugs after marihuana.

One-third of all 1981 high school seniors, 32 percent, indicated having at least tried stimulants without medical supervision. And one-half of these said that they had used the drug in the prior month. All these statistics show a continuing increase over the past 3 years, but a particularly sharp increase from 1980 to 1981.

The researchers who conduct the High School Seniors Survey for us each year indicated that they believed that some of those who reported stimulant or amphetamine use in the last few years have erroneously included the use of over-the-counter stay-awake and diet pills, as well as look-alikes in responding to these questions.

We at NIDA agree and we suspect that much of the dramatic increase in stimulant abuse is a direct function of the large increase in the sale of both over-the-counter stimulants and mail order pseudoamphetamines.

This belief is buttressed by a recently reported survey from the Addiction Research Foundation of Canada, a collaborating center of the World Health Organization, which surveyed high school seniors in the Province of Ontario, which found, as our survey did, that stimulant use was the one drug category which was showing a substantial increase.

Their survey did distinguish between amphetamines and prescription stimulants and nonprescription stimulants, and found that the bulk of the increase was in nonprescription stimulants, and that there were six times as heavy a use of nonprescription stimulants, which would include look-alikes and over-the-counter diet pills, as the use of actual amphetamines.

Mr. RAILSBACK [presiding]. Dr. Pollin, we had better recess for about 15 minutes. We will be back after the vote.

[Recess.]

Mr. RAILSBACK. Dr. Pollin, why don't you continue?

Dr. POLLIN. Thank you, Mr. Railsback.

When we broke, I was summarizing the data which indicates that stimulant use has been the one category of drug use among high school seniors that has shown an increase, and quite a significant increase over the past several years, and that we have reason to believe that the bulk of that use is actually made up of look-alikes and of legal over-the-counter diet aids and pep pills.

Just to visually emphasize the extent of that increase and the contrast, I would like to call your attention to the chart which is displayed, which shows daily use of marihuana, which is the green line; and stimulants, the blue line, for the past 7 years.

Note that the scales are different: The levels of use are very different. However, trends, which is what we are interested in emphasizing here, show that marihuana—both daily use and current use—has decreased significantly since 1978. There has been a one-third decrease in daily use of marihuana during that period of time.

Stimulants have shown just the opposite trend. During the past year, they have shown a dramatic and very disconcerting near-doubling in terms of percentage of high school seniors using them.

The DAWN system, which monitors emergency room visits and medical examiner data, shows that amphetamines and over-the-counter diet aids, during this same time period, have shown similar substantial increases.

And in DAWN, it is likely, as it is true in the High School Seniors Survey, that the self-reported use of amphetamines actually includes look-alikes and diet aids, which implies that the use of those products have increased much more substantially than any of our current data systems can document with precision.

I will only briefly mention that there are serious physical health effects due to these over-the-counter and look-alike stimulants. Subsequent witnesses will be testifying in detail about those effects.

In the interest of time, let me move on. The reason that we are particularly concerned about these substances has to do not only with the physical health effects, but in particular with the developmental dangers that they pose for young Americans.

For maturing adolescents, the major danger in drug abuse is developing a pattern of use of drugs as a shortcut to pleasure, and subjective highs as a substitute for satisfaction derived from realistic achievements.

There is a danger that this shortcut to pleasure, experienced before adolescents have learned the necessary skills and attitudes to be productive adults, will come to dominate and shape their subsequent development and lives.

Easy availability of legal highs increases the likelihood of this developmental pattern's emergence.

We don't have hard evidence as yet, but we have much reason to believe that these kinds of legal stimulants, may indeed, provide the same kind of steppingstone to the use of harder, more well-known drugs as marihuana does.

Let me also only briefly summarize NIDA's efforts and actions in response to the recent awareness of how significant is the problem of this category of drug abuse. We have convened a task force on

the look-alike drug problem, and have begun to coordinate with other Federal agencies in the development of strategies for actions against these substances.

Included in new or proposed initiatives are the following: First, it is essential that we improve our data collection so that we can say with certainty what proportion of the stimulant abuse, as well as the increase in stimulant abuse that we know has taken place, is derived from the look-alikes, from true amphetamines, or from the substantially increased marketing of diet aids and pep pills.

The 1982 High School Seniors Survey, the data from which will be available in the fall, will, for the first time, distinguish between amphetamines, look-alikes, and over-the-counter diet aids. And when next we meet, we will be able to provide very substantial and empiric data with regard to the contribution made by these different categories.

NIDA has been quite active in alerting the professional community and the general public to the look-alike drug problem. Through ongoing activities with State agencies and with the National Parents' Movement, we have contributed relevant data and information in their efforts to facilitate the passage of State and local legislation to control the manufacture and distribution of look-alike drugs.

Our data indicates that as of June 8 of this year, 30 States had passed look-alike legislation, and 9 States were now considering such legislation.

There is no doubt that there has been substantial movement in this area over the past several years, and this committee deserves much of the credit for having called attention to this problem, and having helped to move the States as well as Federal agencies in the helpful direction in which it has gone.

Mr. SCHEUER. Will the witness yield for a question at this time?

Dr. POLLIN. Certainly.

Mr. SCHEUER. You have described the proliferation and the number of States that have tried to address the question of look-alike drugs. My question to you is, may not this be intrinsically a Federal question? And may not Federal legislation be the answer, rather than trying to get 50 States, through 50 varying laws, to cope with the problem successfully?

And, if in your opinion, some kind of Federal legislation is in order, what would be the area it should seek to cover, and what would the approach be?

Dr. POLLIN. Mr. Scheuer, as you know, NIDA is not primarily involved in the enforcement area, and I don't feel that I, personally, can really speak to the relative merits of——

Mr. SCHEUER. What about the health area?

Dr. POLLIN [continuing]. Enforcement options. My own personal view is that it would be desirable for the reasons outlined by the prior witness to have available both State and Federal enforcement opportunities and legislation.

But, further, I believe that basically, in the long run, our greatest need is to try to accomplish the reduction in demand and the increase in social disapproval and concern about health consequences of this category of drugs that we have accomplished during the past 3 years with regard to marihuana.

It is our belief that the reason for the one-third decrease in the daily use of marihuana by teenagers clearly relates to the fact that there has been a substantial increase in their concerns about marihuana's health risks, and there has been a substantial increase in the social disapproval of marihuana by their peers.

This has not been true—in fact just the opposite has been true—for stimulants. We hope to be able to bring a new focus to the problem of stimulant/look-alike abuse that will duplicate what we have been doing in the area of marihuana.

And ultimately, it is this kind of demand reduction which, along with effective and vigorous law enforcement, will be part of any successful dealing with this problem.

Mr. SCHEUER. Thank you.

Dr. POLLIN. In summary, Mr. Chairman, NIDA believes that the issue of legal recreational drugs is a serious national problem and deserving of the attention that this hearing constitutes.

Many researchers are convinced that there are developmental sequences in drug use, that legal drugs can be an integral and significant part of this sequence, and that their use may precede and predispose to the use of illicit drugs.

These substances appear to show a substantial current increase in use when most other drugs are showing a decrease among teenagers.

For these reasons, NIDA will place increasing emphasis on better data collection and prevention efforts targeted at look-alikes.

I will be glad to answer additional questions.

[The prepared statement of Dr. Pollin appears on p. 69.]

Mr. RAILSBACK. Thank you very much, Dr. Pollin. You made an excellent statement.

What about the problem of non-look-alike drugs—the pills containing uncontrolled substances which do not resemble the controlled substances? How does this compare with the look-alike problem?

Dr. POLLIN. We need the kind of epidemiologic data that will be available later this year, so that we can state with precision the comparative size of these two problems.

I believe we will find that use of these non-look-alike, over-the-counter stimulants and depressants is as great or perhaps even greater than use of look-alikes.

Mr. RAILSBACK. Is the threefold combinations of caffeine and——

Dr. POLLIN. PPA and ephedrine.

Mr. RAILSBACK. Not illegal now, even when combined?

Dr. POLLIN. They are not currently illegal. But I believe that FDA is looking into the issue, and will testify subsequently this morning to the question of possible new regulatory consideration of those kinds of combinations.

Mr. RAILSBACK. It seems to me that when they are sold as a combination, this might constitute a new substance that could be harmful, and should be regulated.

I am going to call on Mr. Shaw.

Mr. SHAW. I am fascinated by your charts, and particularly impressed by the evidence that marihuana use is decreasing, and by the reason that you gave; it is decreasing because of education and concern over the health aspects.

Do you find any trace in your studies that stimulants are taking the place of marihuana among those who are using it? In other words, are those that have given up marihuana now turning to the stimulants?

Dr. POLLIN. First, let me emphasize, again, Mr. Shaw, the point I made, perhaps too briefly, that we have shown these two curves on different scales so that actually the level of use of the stimulants, is only one-quarter or one-fifth as high with regard to daily use, perhaps half as high with regard to use during the past month, as of marihuana.

At this point, we don't know to what extent there is, indeed, a trade-off by individuals moving from one drug to the other.

However, it is clear that the overall use of drugs by high school seniors does seem to be decreasing, and it is our impression that overall use of drugs and acceptance of drugs, which had been increasing sharply and dramatically from the early sixties through 1978–1979, has really turned around, and has begun to come down.

Mr. SHAW. On your chart, where would you place alcohol use by high school students? And which way would that trend line be going?

Dr. POLLIN. Daily use of alcohol throughout this time period when daily use of marihuana was sharply increasing remained essentially flat. Binge drinking, that is, drinking five drinks or more at any time during the past 2 weeks, has shown some tendency to increase, and is at a very disconcertingly high level.

Cigarette smoking, which is the other most widely used drug—nicotine, that is—has shown the same kind of decrease that marihuana has shown during the same time period. It has reduced approximately a quarter during the past 4 years.

While we are encouraged by the decrease in marihuana use, what is very disconcerting and deserves emphasis is that at this point in time, there are more current users of marihuana, despite the decrease—31 percent have used marihuana during the past month—than there are current smokers of cigarettes, which constitute only 29 percent.

Mr. SHAW. It would be interesting to know how many of the same people we are counting in each one of those statistics.

Dr. POLLIN. Yes, that is very important, and we hope to be able to initiate new surveys that can get at that key question.

Mr. SHAW. Thank you.

Mr. RAILSBACK. Mr. Gilman.

Mr. GILMAN. Thank you, Mr. Chairman.

We heard some testimony this morning from Attorney General Fahner about the need for a Federal statute. Are you in agreement with that, Dr. Pollin? Do you feel that there is a need for a Federal statute in this area?

Dr. POLLIN. Personally, and this is a personal, not a departmental position, I do feel that it would be useful to have both Federal and State statutes.

Mr. GILMAN. What would you like to see in the Federal statute?

Dr. POLLIN. As I mentioned to Mr. Scheuer, enforcement is not the area where I feel that I have expertise and I would leave that to the other witnesses to speak about in greater detail.

Mr. GILMAN. Has your task force that you have brought together submitted a report?

Dr. POLLIN. It has submitted a report. There are a number of new initiatives which have been begun, or which are being planned.

Mr. GILMAN. And is the issue of look-alike drug abuse being given the proper attention by the White House drug policy staff from the standpoint of coordinating an effective overall strategy on this problem at the Federal level?

Dr. POLLIN. I believe it is, Mr. Gilman. There is widespread, growing recognition, importantly helped by this committee, in recognizing the fact that among our young people, stimulants are, after marihuana, the most widely used drugs.

And we have reason to believe that among the stimulants category, look-alikes and legal over-the-counter stimulants play a much larger role than do the actual amphetamines.

Mr. GILMAN. We understand there is a strategy paper that is being circulated amongst the narcotic enforcement and narcotic treatment agencies. Have you had some input into that strategy paper?

Dr. POLLIN. Yes, we have, Mr. Gilman.

Mr. GILMAN. Has there been any suggestions made in the strategy paper with regard to look-alike drugs?

Dr. POLLIN. I wouldn't like to, at this point, speak to the content of it before it is released, but I think you will find that the matter is adequately addressed in that strategy document.

Mr. GILMAN. Thank you.

Thank you, Mr. Chairman.

Mr. RAILSBACK. I just have one other question.

Is there any evidence, scientific or otherwise, that supports your statement that a dependence can develop from using these legal over-the-counter stimulants that may lead to future drug abuse?

Dr. POLLIN. The evidence is contradictory at this point, Mr. Railsback. There are a number of studies. In animal studies, the actual, so-called reinforcing properties of these substances appears to be quite low.

In human studies, when one inquires among groups of addicts, what their subjective rating would be for the extent to which they like or they feel the need for different categories of drugs, both caffeine and nicotine come out surprisingly high.

Mr. RAILSBACK. You mean as leading to further drug abuse?

Dr. POLLIN. No, not as leading to addiction. There heroin addicts in treatment were asked to rate 10 different drug categories in terms of how much they like them, and how much they need them. This kind of need and liking score has been found to be an important predictor of the extent to which individuals become dependent on, though not physically addicted, to different drugs. And caffeine and nicotine rates surprisingly high. We could submit a summary of that study for the record if you like.

So that, based on those kinds of data as well as on what we have learned from intensive evaluations of addicts as they describe the sequence of their subjective experience that led them to heavy drug use, there is reason to believe that any kind of subjective high can

play an important role in contributing to a pattern of later harder drug use.

Mr. RAILSBACK. Thank you very much. We appreciate your testimony.

Dr. POLLIN. Thank you, Mr. Railsback.

Mr. RAILSBACK. I would like to call Dr. Sorell Schwartz from the Department of Pharmacology at Georgetown University as our next witness.

Dr. Schwartz, we want to welcome you. You may proceed, by either reading or summarizing your statement.

TESTIMONY OF SORELL L. SCHWARTZ, PH. D., DEPARTMENT OF PHARMACOLOGY, GEORGETOWN UNIVERSITY

Dr. SCHWARTZ. Thank you, Mr. Chairman.

First of all, I am pleased to have been invited to testify before the committee, and welcome the opportunity to discuss the problem of look-alike drugs. I have prepared a written statement for the record, which has been submitted, and I will just summarize that statement at this time.

My involvement with the problem of look-alike drugs arises from my activities as an advisor to the U.S. Postal Service on mail advertising and sale of look-alikes and other drug products.

There still appears to be some belief that the major problem with look-alikes is not with their contents, but that they are misrepresentations of other drugs. In fact, the implication has been made that the ingredients are harmless stimulants, and that the drug user is better off with the look-alike than with the real drugs of which they are counterfeits.

The distributors have implied this, and I am aware of unofficial comment from FDA personnel also expressing this view.

Generally, look-alikes contained phenylpropanolamine, or PPA, and/or ephedrine and/or caffeine. All three are available as over-the-counter, or OTC, drugs. PPA and ephedrine are used as decongestants, though they are not generally used together.

PPA alone and PPA with caffeine are used in the OTC diet aids. PPA and ephedrine are chemically related to amphetamines, though they do not have the same ability to produce a euphoria, the sense of well-being, which makes amphetamines the subject of abuse of drug-seeking behavior.

There is increasing evidence, published and unpublished, indicating that PPA is causing hypertensive episodes in some individuals. Beginning is Australia, and then in this country, there have been a collection of incidents of hypertension reportedly caused by the use of PPA in diet aids.

The citations for the published reports of these effects are given in my written statement.

Ephedrine also increases blood pressure and is certainly additive to the effect of PPA. I believe that there is a high likelihood that it may be synergistic. That is, that the two drugs potentiate each other's effects. The sum total of effect is greater than the additive.

The combination of these two drugs, and perhaps along with caffeine, carries an obvious potential for harm. This potential has apparently been realized. The fact is that the phenylpropanolamine

and ephedrine, though they are like amphetamines, do not give the effects on the central nervous system or have only very weak effects, and the attempts to attain that effect leads to overdosage and effects on the cardiovascular system.

Pathologists at the Center for Forensic and Environmental Science at the University of New Mexico's School of Medicine, have carefully reviewed the autopsy data on three individuals in their late teens and early twenties, who died of cerebrovascular accidents, strokes.

They all had cerebral hemorrhage, intracerebral hemorrhages which were not caused by aneurysms, the usual cause of strokes in young people. On the basis of reports of look-alike usage, a review of emergency room records for hypertensive crises associated with the use of look-alikes, and on theoretical grounds, the pathologists there consider look-alikes as a likely possibility of cause of the deaths of these three individuals.

I have also discussed two other cases of stroke with a physician in New York who provides careful documentation, which allows for a conclusion of look-alikes as a probable cause.

And you have heard of similar situations in the State of Illinois. There are also published and unpublished reports of psychotic episodes associated with PPA and ephedrine. It is likely that once physicians are informed of possible causal relationships of PPA alone, or in combination with ephedrine or caffeine, with hypertensive episodes, strokes, and death, many more incidences of look-alike-caused injury of death will become evident.

I believe that part of the problem lies with the Food and Drug Administration. I have a great deal of difficulty in understanding how the agency can act on starch blockers on the basis of unproven safety, while allowing various combinations of PPA with ephedrine or caffeine to be marketed.

This is especially true in the light of the failure of the FDA to adequately investigate the carefully studied deaths in New Mexico. In my written statement, it discusses one aspect of this FDA investigation.

I might add that what protection the population has received from the Federal Government concerning the distribution of look-alikes has been from the Postal Service, by a very dedicated group of postal inspectors within the Special Investigations Division, and an equally persistent group of attorneys within the Consumer Protection Division.

However, the laws that the Postal Service has to work with were not really designed to handle the breadth of problems associated with the look-alikes.

But at least the Service has been effective in keeping the distributors from operating with complete impunity, and in bringing the issue before the public.

I would be more than happy to answer any questions you might have.

[The prepared statement of Dr. Schwartz appears on p. 76.]

Mr. RAILSBACK. Thank you very much. We appreciate your coming.

I tried to read your written statement while you were giving your summary, and is it fair to say that you are very much con-

cerned about this combination, whether used as a look-alike, I take it, or whether it was a non-look-alike, that, in your opinion, may be used in excess and may have the effect of causing hypertension or hypersensitivity?

Dr. SCHWARTZ. Yes, absolutely. My concern, there are two sides. One is the imitative effects of look-alikes, and the other with the ingredients.

The imitative effects have one potential problem, and that is that an individual taking a look-alike is not going to get the central nervous system effect, the euphoria that he will get with amphetamines, taking an equal number—taking a single capsule.

Mr. RAILSBACK. Is that because PPA simply does not produce that effect?

Dr. SCHWARTZ. That is right.

Mr. RAILSBACK. Does it cause blood vessels to constrict?

Dr. SCHWARTZ. Well, it won't—no, it has the effect to constrict blood vessels, but it won't produce the stimulation. Now, what the individual is likely to do, is he increases dosage in order to try to get that effect, which, of course, increases the possibility of cerebrovascular or cardiovascular effect.

But what it also does is give him, if he doesn't realize the look-alike is a look-alike, give him a false sense of his tolerance to amphetamines. And the next time he purchases something on the street which might not be a look-alike, but which might the real amphetamines, he is likely to say, "Well, last time, it took my five capsules to get anything, so I might as well start."

Well, if he takes five capsules of amphetamines, he is going to—if he doesn't die, he is probably going to have a rather severe psychotic episode, which could lead to his death or certainly injury.

Now, the other side of the coin is the components themselves. I happen to have advised the Postal Service that claims made for diet aids through the mail that they are safe and effective, represent a fraudulent representation in the fact that they are neither safe nor effective.

I think that the Food and Drug Administration has dragged their feet on the matter of diet aids, notwithstanding the fact that the use of appetite suppressants is a very poor way to control obesity, the fact is, that these drugs do not have the appetite suppressant activity which is represented for them, both by television advertising and, for that matter, by the panel who wrote that report.

As has been implied, those drugs, those over-the-counter diet aids, also serve—are used by young people, go into the drug stores and buy them, and I have heard reports from DEA, either a DEA investigator or a postal inspector, of kids who have done this.

My concern is primarily—my immediate concern is with the combination of phenylpropanolamine and ephedrine. But I believe that the widespread use of phenylpropanolamine alone or in combination with caffeine as used in the diet aids, presents a similar problem.

Mr. RAILSBACK. Have you had occasion to contact the FDA to express your concerns? Do you know if anyone has done that?

Dr. SCHWARTZ. Well, yes. I have worked with the Postal Service, and my initial response, when this all began a while back, was, "I

think you ought to contact the FDA, because this combination is certainly potentially harmful."

I was surprised when I heard the FDA wasn't particularly enthused, and I had some unofficial contacts which confirmed the lack of enthusiasm—personnel—and this comment that, "Well, you know, maybe they are better off taking that than the real thing."

It is a somewhat cynical point of view, and I think that cynicism persists. I received from counsel, from your committee's counsel, a letter, either proposed or to be sent, or has been sent out, by the FDA, to the producers, or manufacturers, of look-alikes.

And the statement is, "The triple combination product"—that is, PPA, ephedrine, and caffeine—"is not the kind of product that is or ever was intended to be included in the over-the-counter drug review."

And it goes on to say, "The individual active ingredients in this triple combination at certain levels and for certain indications alone, and in some combination of two, are deferred to an ongoing, over-the-counter drug review."

Well, what they are saying is that, "We are reviewing the situation, but you can't market anything with the triple combination." And that, I think, is a rather cynical approach.

It means, therefore, that all they have to do is drop caffeine, and they are scot-free, which means they market PPA and ephedrine. And that is the most unproven combination of all.

Now, the FDA has come under some criticism for its foot-dragging on the diet pill issue, and I understand the problems, but I do think that if, in fact, they try to act on look-alikes by banning two-combination drugs, either phenylpropanolamine and caffeine or phenylpropanolamine and ephedrine, or ephedrine and caffeine, then they will be accused—could be possibly accused of being discriminatory and would be forced to act on the over-the-counter diet aids, which would then bring down the, perhaps, response from more reputable drug companies, which are producing those diet aids.

I understand the position therein. Unfortunately, I don't appreciate the way they have responded to it.

Mr. RAILSBACK. Are there others in your profession, with your background, that share your views; or do they result from your your experience with the Postal Department?

Dr. SCHWARTZ. I would say that, first of all, in spite of all of the lights and cameras and meetings and so forth, many physicians and many toxicologists are not familiar with what a look-alike is.

I would say that anybody, any toxicologist or pathologist who has studied the data concerning look-alikes has come to the same conclusion that I have. That these preparations represent a clear and present danger in and of themselves, irrespective of whether they do or they don't look like a manufactured product.

Mr. RAILSBACK. What would you do about non-look-alikes in combination?

Dr. SCHWARTZ. Well, my understanding, and perhaps this can be clarified by somebody from the FDA, my understanding is that the Food and Drug Administration has the authority to declare a combination as unacceptable for marketing. And that if they do that, if they decide to ban a combination such as phenylpropanolamine

and ephedrine, it wouldn't make any difference whether it was from a look-alike drug or a non-look-alike drug, it would be the combination that is controlled.

Now, my understanding is that the respondent has the burden of proof to demonstrate safety.

Now, there is an expression around this town in health matters that all the—that everybody in the health agencies think they are doctors, except the doctors. They think they are lawyers.

The problem is, I don't want to get into that. That is my understanding.

If it is not the situation, then certainly some legislation is needed toward that. But, I feel, from my experience, and I have had experience with FDA problems and regulations for about 20 years working, interacting, and so forth, is that the FDA currently has the authority to ban the combination of phenylpropanolamine and ephedrine, and certainly, they should have—they have recently opened for public comment, in 1977, a report of the panel—certainly that should have been done earlier, but that is water over the dam.

Mr. RAILSBACK. Is the combination of PPA and ephedrine more dangerous if used in excess, in your opinion, than caffeine with one or the other?

Dr. SCHWARTZ. In my opinion, I think that they are more dangerous, but I would like to say that it is comparative. It is more dangerous. I believe that PPA used by people who are obese and who potentially have high blood pressure, the numbers of people that will use the drugs, I think it can be predicted that there will be morbidity, if not mortality.

Mr. RAILSBACK. I just want to say that your testimony has been very important, and should trigger further inquiry by this committee or any of the congressional committees that have jurisdiction over this matter.

Are there any questions from counsel?

Well, then I want to thank you very much. I see we have a vote on.

Dr. SCHWARTZ. Thank you, Mr. Chairman.

[Recess.]

Mr. RAILSBACK. Mr. Lents, would you like to introduce Mr. Goodridge?

TESTIMONY OF CHARLES LENTS, COUNSEL, REGULATORY AFFAIRS, WARNER-LAMBERT CO., ACCOMPANIED BY WILLIAM G. GOODRIDGE, JR., DIRECTOR OF CORPORATE SECURITY, WARNER-LAMBERT CO.

Mr. LENTS. Yes, I would. Mr. Chairman, this is Mr. William Goodridge, he is director of the corporate security office of Warner-Lambert Co.

Mr. RAILSBACK. You may proceed. We are aware of some of the efforts that you have been making, and feel very good about them. But please go ahead and tell us.

Mr. LENTS. Thank you.

Mr. Railsback, members of the committee, Warner-Lambert is pleased to have the opportunity to submit a written statement, and to appear before the committee, on behalf of its Capsugel Division,

which supplies empty gelatin capsules to the pharmaceutical industry.

My name is Charles E. Lents, counsel, regulatory affairs, Warner-Lambert Co. For the past year, I have been reviewing the controlled drug look-alike problem in an effort to ascertain what steps Capsugel can take to minimize this serious public health problem.

As I indicated, I am accompanied today by Mr. William Goodridge, director of corporate security of Warner-Lambert. Mr. Goodridge has been involved in the development and implementation of certain efforts which Capsugel has taken to discourage the production and distribution of controlled drug look-alikes.

I will discuss these efforts later in the presentation, which will be a summarization of the statement which has been submitted for the record.

As we indicated in 1981 to the committee, Warner-Lambert's Capsugel Division, and its predecessors have achieved considerable expertise in the production of gelatin capsules for medical and therapeutic purposes.

We have been making capsules for nearly 100 years, having begun in 1888. Capsules are manufactured and marketed on a worldwide basis to other pharmaceutical companies which fill them with their own chemical ingredients, and then market them as their own products with their own trade names and individual markings.

Capsules are produced at our Greenwood, S.C., manufacturing facility, as well as at other manufacturing locations in Europe, Asia, and Latin America.

To many, the controlled drug look-alike problem may appear to be a phenomena of the present day, but its roots, as far as society and industry are concerned, are deep and closely parallel to the drug problem of the late sixties and early seventies.

The traumatic effect of the look-alike problem has been more pronounced within the last year. Because we have witnessed the youth of our Nation falling victim to the insidious enticement of individuals purporting to help alleviate the drug problem by diverting drug abusers to legitimate, over-the-counter drugs.

In reality, their motives are strictly profit oriented.

Last year, we informed you that Capsugel had initiated certain actions which we felt would discourage improper use of its capsule products. Our actions included the stopping of imprinting of copy-on capsules of certain colors, and the actual curtailment of the manufacturing of specific capsule color combinations and sizes, which we determined to be popular in the illicit drug trade.

We then sent a letter to our capsule customers asking for verification that customers' products produced with Capsugel-manufactured capsules, were being distributed in accordance with applicable local, State, and Federal laws.

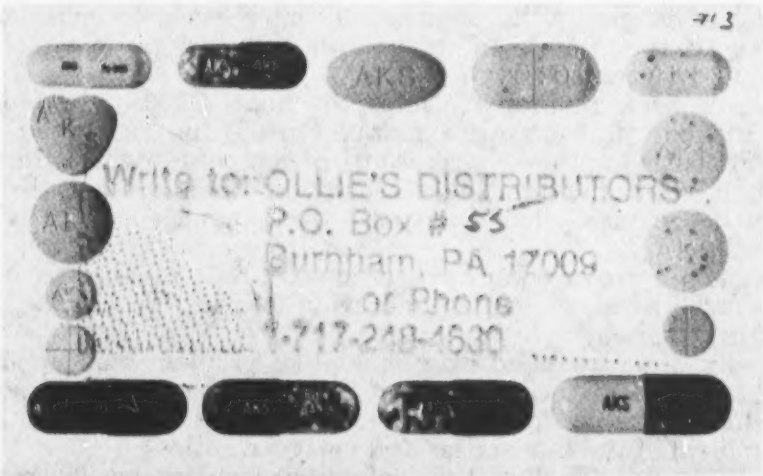
We also required complete labeling, including package inserts, if applicable, be submitted to Capsugel. The letter said that after reviewing such material, a determination would be made whether the finished product was a legitimate generic for which capsules would continue to be supplied, or a look-alike substitute for a controlled substance.

Orders for these capsules would not be accepted. The above was a voluntary good-faith effort on Capsugel's part, and at that juncture, we believed that we had taken appropriate action to curtail the supply of capsules in the size and color combinations reportedly favored as controlled drug look-alikes.

In recent months, however, there has developed a trend to utilize capsules with nonimitating color combinations and/or markings which, we are told by Federal officials, are then popularized through word-of-mouth advertising and marketing practices as containing controlled drugs as the active ingredients.

I would like to submit to the committee for your examination some promotion cards with were placed on all cars in a mall in New Jersey in the last week. I think you will find them interesting..

[The information follows:]



Mr. LENTS. The public, in general, and our youth in particular, are being victimized by these misleading practices, which often result in physical injury or even death to users.

In late 1981 and early 1982, Warner-Lambert Co. and its Capsugel Division initiated a program to ascertain what additional steps could be taken to curtail this reprehensible practice.

We contacted each of the involved Federal regulatory and law enforcement agencies, as well as the staff of this committee, for advice and counsel.

We received an excellent reception, encouragement and assistance from all parties.

From these discussions, we determined that we faced three problems as a capsule manufacturer: The first relates to the hundreds of colors and color combinations which can be used to produce look-alikes and now the non-look-alike look-alikes.

The second concerned our desire not to be a deterrent to the marketing of legitimate generic products. The third related to potential allegations of improper restraint of trade.

As we previously indicated, Warner-Lambert's Capsugel Division operates on a global basis. At a meeting earlier this year, in Basel, Switzerland, attended by many of our key worldwide capsule personnel. We addressed the current U.S. problem and issued instruc-

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tions to be on the lookout for similar trends developing in international countries.

We advised them to be especially alert to attempts to improperly divert internationally produced capsules into the United States. A specific action program was developed, and communicated within the Capsugel Division on a worldwide basis.

This program has already paid dividends. In late July of this year, we were informed that a party in the United Kingdom wanted to place an order for 50 million black-black and yellow-yellow capsules. As you know, black-black and yellow-yellow are the most popular controlled drug look-alike color combinations.

It was ascertained that the order was being placed by a third-party company who were trying to obtain capsules on behalf of a U.S. company who were unable to obtain the capsules from Capsugel in the United States.

It is thus evident that controlled drug look-alike manufacturers, not being able to obtain capsules in the United States, may turn to international areas to obtain their supplies, even though the cost would undoubtedly be higher.

Needless to say, our international organization would not honor this request. We are concerned, however, that we may not always be able to detect such orders and potential domestic or international diversions may occur, due to the very large number of possible capsule color combinations.

In recent months, Capsugel has decided to initiate a number of new actions, which we hope will further discourage the manufacturers and distributors of these products. These steps, which will be instituted in the United States, include a requirement that all Capsugel customers sign a statement and continuing guarantee that any capsules they purchase will not be used to manufacture controlled drug look-alikes.

We have also decided to program our computers with customers' names, capsule color combinations purchased, and copy imprinted on such capsules.

We will provide this information to appropriate law enforcement agencies when such agencies are involved in an official investigation.

Your letter inviting us to appear here today asked that we discuss the continuing guarantee proposal. Its rationale is based upon our desire to make it clear to prospective customers that Capsugel will not supply capsules except under the conditions spelled out in the guarantee.

We believe the statement of continuing guarantee will deter unscrupulous manufacturers from using capsules to make controlled drug look-alikes or products that do not specifically imitate the appearance of controlled drugs, but may be advertised and sold as containing controlled substances.

Also, the form will provide law enforcement authorities with an investigative tool which may be helpful to them in identifying persons or firms who may be violating the law.

The staff of the select committee has been of great assistance to us in developing the proposal. Through them, a recent draft has been made available to various members of the regulatory and law enforcement community.

We have received comments, suggestions and sufficient encouragement, such that Warner-Lambert intends to fully implement the program in the near future. As you will note, we will require all Capsugel customers to sign and certify to Capsugel that no capsules heretofore or hereafter obtained from the supplier, are, or will knowingly be used by purchaser or to purchaser's knowledge, by its distributees in the production, encapsulation, packaging, or marketing of any product which is in violation of the Federal Food, Drug and Cosmetic Act, the Controlled Substances Act, or any corresponding law of any State or local authority.

Also, the purchaser must specifically warrant that no capsules heretofore or hereafter obtained from the supplier are or will be knowingly used by purchaser or to purchaser's knowledge by its customers or distributees in the production, encapsulation, packaging, or marketing of any illegitimate product or any legitimate product, which is likely to confuse, mislead or be falsely misrepresented to any person as being the same as or similar in content to a controlled substance.

Last, the continuing guarantee provides that purchaser hereby authorizes the supplier to provide a copy of this document to governmental departments or agencies having jurisdiction to determine whether or not the capsules and the products of which they are a part, are being utilized in conformity with applicable Federal, State, and local laws.

We have discussed the statement and continuing guarantee with outside legal counsel, and are of the opinion that a knowing violation of its terms would be actionable under a number of Federal statutes which directly or indirectly bear upon the activities involved in the distribution of controlled drug substances and their look-alike counterparts.

We also believe that the statement and continuing guarantee has a tie-in with recent look-alike legislation passed by a number of States, as we have heard this morning. We specifically reviewed the statutes of the State of New Jersey, where Warner-Lambert has its headquarters, and they, as you know, have recently adopted an amendment to the New Jersey Controlled Dangerous Substances Act, prohibiting possession, manufacturing, and trafficking in look-alike drugs.

While Warner-Lambert and its Capsugel Division are of the opinion that the above proposals will help to alleviate the controlled drug look-alike problem which involves capsules, it will, of course, do nothing to prevent the further developing problem which involves tablets and powders, as you have seen in the card that I gave you earlier this morning.

In fact, existing evidence supports the conclusion that non-look-alike's in the form of pill, tablet, and powder products are now appearing using different ingredients other than caffeine, phenylpropanolamine, and ephedrine sulfate.

Thus, a multifaceted approach is needed which will involve all the agencies and parties appearing before the select committee today. It does appear that some overriding Federal legislation is needed that will address the problem in a generic manner.

We, therefore, would favor appropriate amendments to the Federal Food, Drug, and Cosmetic Act and the Controlled Substances

Act which would specifically prohibit the manufacture, distribution, and trafficking in controlled drug look-alikes in any product form.

We thank the select committee for giving us this opportunity to express our views on this national problem. We commend your efforts to seek viable solutions to the dangers which controlled drug look-alikes represent to the public and especially the youth of our Nation.

Thank you, Mr. Railsback.

[The prepared statement of Warner-Lambert appears on p. 79.]

Mr. RAILSBACK. I want to thank you very much.

Mr. Goodridge, you don't wish to add anything?

Mr. GOODRIDGE. No.

Mr. RAILSBACK. All right. Then I would ask that your cards be introduced into our record. I think we may have some from the earlier hearing.

How many other firms are in the business of manufacturing these capsules in large numbers?

Mr. LENTS. In the United States, there are three major firms: Capsugel, Elanco Division of Eli Lilly, and R. P. Scherer. I think Smith Kline and French also has a number of machines for making capsules, but I believe they are all for internal use.

Mr. RAILSBACK. I see.

Mr. LENTS. So there are essentially three manufacturers.

Mr. RAILSBACK. Are there activities by those other manufacturers similar to your activities to try to monitor and maybe do something about the inappropriate use of the capsules?

Mr. LENTS. I have no specific knowledge and I don't believe anybody in our company has talked with any of the other capsule manufacturers. We have been very careful and concerned about allegations of restraint of trade.

But at the time of your hearings last year, there was an indication that at least Eli Lilly had taken some actions which were similar to ours.

Mr. RAILSBACK. What has been the reaction of your customers that have had to meet your requirements?

Mr. LENTS. Well, we have had a pretty good reaction from the majority of our customers. There have been some complaints. We have had some indications that we might face some civil antitrust action. There have been no suits, however, filed to date.

But I must say that there have been also very few people who have attempted to obtain the most popular of these look-alike products since we have put out our proposal.

Mr. RAILSBACK. In other words, the yellow- or the black-colored capsules?

Mr. LENTS. Yes, I think that probably the best example is the attempt to go to Europe to obtain these capsules. I think we have had some effect on these people.

Mr. RAILSBACK. In that regard, did you have evidence that the American firm was actually going to use the British firm to supply the capsules that you would not supply?

Mr. LENTS. No; this was—as I was informed—this was a third-party, broker-type concern that went to our people to order the

capsules. When we tried to check back and see who it might be, we were not really successful in obtaining any information other than the fact that it was for a U.S. firm who had been denied capsules by our facility here.

Mr. RAILSBACK. I see. I have no further questions. Does counsel have any questions?

Mr. CARPENTIER. Mr. Lents, have any of your established customers raised any complaints regarding the tightening of your procedures in the selling of your capsules?

Mr. LENTS. None of our major customers have raised any complaint about it. I don't believe that there are going to be complaints by good legitimate people that produce pharmaceuticals. I think the majority of them are good, honest manufacturers. I don't believe that we are going to get any complaints to speak of about this policy.

Mr. CARPENTIER. I did want to add, Mr. Chairman, that the staff, Ms. Yager and Mr. Gilbert, thank you for giving us the opportunity to be able to assist you in your effort, and do commend you, and Warner-Lambert, and Mr. Goodridge, for taking this initiative which shows a high sense of responsibility within the private sector. And we thank you again for that.

Mr. LENTS. Thank you, Mr. Carpentier.

Mr. RAILSBACK. And I also, on behalf of the committee, want to thank you sincerely. Maybe some of the other companies will follow procedures similar to yours.

Mr. LENTS. We have had such an excellent coordination with your staff that this might be something that they could follow up on, and I do want to commend them for their very good work in this regard.

Mr. RAILSBACK. Good. Thank you very much. We are pleased to have you.

[Recess.]

Mr. GILMAN [presiding]. The committee will come to order, and we ask Mr. Hile, the Associate Commissioner for Regulatory Affairs, Food and Drug Administration, to present his testimony.

TESTIMONY OF JOSEPH P. HILE, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY ARTHUR N. LEVINE, DEPUTY CHIEF COUNSEL FOR LITIGATION, FOOD AND DRUG ADMINISTRATION, AND EDWARD C. TOCUS, CHIEF, DRUG ABUSE STAFF, FOOD AND DRUG ADMINISTRATION

Mr. HILE. Thank you very much, Mr. Chairman. I would like to take a moment, if I may, to introduce two colleagues that I may call upon later to assist me in responding to your questions. Directly behind me is Mr. Arthur Levine, our Deputy Chief Counsel for Litigation; next to him is Dr. Ed Tocus, the chief of our drug abuse staff in our Office of Drugs.

Mr. GILMAN. We welcome your assistance, and feel free to summarize your statement, if you like, and you can put the entire statement into the record if you would like to.

Mr. HILE. I would like to do that, Mr. Chairman.

Mr. GILMAN. The full testimony will be included in the record. And you may feel free to summarize your testimony.

Mr. HILE. Thank you.

Mr. Chairman, we welcome the opportunity to participate in this important hearing on look-alike drugs and the public health problem which they represent. Last October, it was my privilege to appear before you and other members of the committee in New Jersey, where we discussed with you the rapid growth of the over-the-counter look-alike phenomenon, and the public health and law enforcement problems associated with it.

We reviewed the role that the Food and Drug Administration felt it could play to reduce the traffic in OTC look-alikes as well as the seizures of OTC look-alike products and the equipment used in their manufacture that FDA had already undertaken against nine major manufacturers of these drugs.

I am pleased to provide you with an update of our activities since that hearing and to describe our future actions in response to recent trends in the illegitimate OTC trade.

In five of the nine cases that were discussed with you last fall, we have settled those cases by consent decrees, and the terms of those decrees vary somewhat. But in the majority, they contain injunctive language prohibiting the manufacture, sale, distribution, or holding of any drug which is a counterfeit as well as any drug which is an imitation under the act.

And the remaining four cases are being actively pursued to reach settlement. In all of the cases where consent decrees have been signed, the decrees ordered the destruction of the finished drugs, capsules, dies, and punches that we seized.

In addition to those nine seizures, we have cooperated with DEA and Florida State officials in seizing approximately 600 pounds of tablets that were marked "LEMMON 714," resembling quaaludes. Those were tablets that did not fall under the jurisdiction of either the State or DEA.

Those tablets have been seized and the court has ordered their destruction.

In a separate development, we undertook an investigation in Wisconsin of a reported firm manufacturing look-alike products on a farm. We investigated that firm under a criminal search and seizure warrant, and the evidence obtained during that investigation indicated that the facility may well have been involved in the manufacturing of counterfeit products. Since that time, however, the firm has gone out of business with no evidence of continuing manufacturing activity.

More importantly, although those two episodes demonstrate our continuing interest in following up every opportunity that is presented to us to investigate reports of the manufacture and distribution of these products, and also reflect our good cooperating relationship with DEA. Our more important activity in the last number of months has been to undertake an investigation of distributors and to consider an appropriate strategy to deal with principal distribution centers for these drug products.

Last December, all of our district offices were requested to conduct an investigation of those distributors that were suspected to be actively engaged in the distribution of OTC look-alike drugs.

Our investigators, acting as potential customers, were instructed to obtain all representations and suggestions made by the distributors that their products could be passed off as controlled substances.

In the opinion of the agency, such evidence could be necessary to take advantage of the imitation drug provision of the act, and thus expand the scope of our authority as it will be brought to bear on the look-alike drug business.

Based on our assessment of the information uncovered during those investigations of distributors, we have concluded that the imitation charges could be brought against several of those distributors. There are 40-some that continue to be a focus of our investigation.

We have available to us injunctive authority over imitation drugs, even though that is lacking for counterfeit drugs.

We now anticipate bringing a third authority to bear against the distributors in the form of an unapproved new drug charge under the act. This is focused on the so-called triple combination.

Toward this end, we will publish a notice in the Federal Register today that confirms the agency's policy. And we have provided a copy of that announcement to the committee. This notice is directed, as I mentioned, to the drugs containing the triple combination of phenylpropanolamine, ephedrine sulfate, and caffeine, and announces that they are now regarded as new drugs, and thus require an application to FDA for marketing approval.

Appropriate regulatory action, as followup to this Federal Register notice with the distributors, is planned.

This use of the new drug authority is a recent development which I will discuss later, but in the way of background, I would like to review some trends in the OTC look-alike trade since the seizures which we took last fall were taken, and which have, in a sense, led us toward this next step.

Our adverse reaction reporting systems have reported only one death attributed to OTC look-alike drugs since the seizures against the nine manufacturers last September. Before the seizures, we were aware of 12 deaths.

We cannot establish a cause-and-effect relationship between this dropoff and our enforcement activities, however.

In fact, the failure to report deaths may be attributable to the mistaken identification of the drug by either the user or the reporter due to the success of the deception in the early distribution of truly counterfeit look-alikes.

We can report with some certainty that the seizures have reduced the traffic in the true counterfeits, which mimic the markings of manufacturers of controlled substances. We believe that in order to evade FDA enforcement action, however, manufacturers are reacting to the seizures by moving away from counterfeiting and toward OTC combinations which do not physically resemble controlled substances. Already, today, they have been described as non-look-alike products. And the use of those products appears to be on the upswing.

Unfortunately, the manufacturers have correctly recognized that the effectiveness of our counterfeit and imitation authorities de-

creases as physical resemblance to controlled substances becomes more tenuous.

However, the predominant formulation in these products is now a triple combination of caffeine, ephedrine, and phenylpropanolamine. Thus, many of these drugs are reachable, regardless of appearance, because this combination of ingredients is now subject to our new drug authority.

For our purposes, the term new drug refers to recognition rather than age. As defined by the act, a new drug is one which is not generally recognized by experts as safe and effective for use under conditions stated on the labeling.

The new drug is thus prohibited from interstate commerce until it receives marketing approval from the Food and Drug Administration.

Now, individually, the three ingredients in the triple combination may not be new drugs. They have been on the market in OTC products for decades, either alone or in combination with other ingredients. Thus, individually, and in some combinations, they have fallen under the purview of the FDA's ongoing over-the-counter drug review, a 10-year effort to determine the safety and efficacy of the more than 700 active ingredients in some 300,000 OTC drug products sold in this country.

Panels of experts involved in the OTC review already have recommended to FDA that all three ingredients individually are safe and effective for use in a variety of OTC products for at least one indication.

For a considerable period of time, it was unclear whether the three ingredients as found in the OTC look-alikes existed together in a triple combination in some legitimate OTC products. If they did, they would fall under the purview of the OTC review, and be potentially exempt from enforcement action until the review's analysis is complete.

However, no OTC products containing the triple combination have been found, aside from the drug abuse products at issue. FDA has therefore determined that the triple combination is outside of the OTC review, and should be regarded as a new drug, because it is not generally recognized by experts as safe and effective for use as described in the labeling.

Case law establishes that such recognition must be based on published reports of adequate and well-controlled clinical investigations.

We recently issued regulatory letters to 14 manufacturers of triple combination products, informing them that these products are unapproved new drugs, and that their shipment in interstate commerce was in violation of the law.

The letters requested that manufacturers advise FDA of steps taken to correct all violations associated with these products, and as of this date, 10 of the firms have advised us that they have stopped manufacturing the triple combination product. We will continue to monitor their activities.

While we are optimistic that our actions will eradicate the triple combination, and have significant impact on the immediate availability of illegitimate OTC products, we know, also, that the new drug charge responds only to one aspect of an evolving problem.

We have reason to believe that manufacturers are already reacting by deleting one of the three ingredients, and thereby, manufacturing a product which falls within the purview of the OTC review, and actually possesses a rational medical use.

To the extent that such a product does not physically resemble a controlled substance, and is generally recognized by experts as safe and effective and used in accordance with its labeling, its abuse, after being removed from a properly labeled package will present a new and challenging enforcement problem.

As the OTC look-alike trade modifies its behavior to avoid violations of the Federal Food, Drug, and Cosmetic Act, it may become increasingly more difficult for FDA to act against these manufacturers and distributors.

The regulatory scope of the Food and Drug Administration is broad, but it does not extend into the area of street abuse, which would require undercover investigations by FDA employees outside the conventional channels of commerce.

FDA can and will continue to contribute toward the reduction of the OTC look-alike trade through its counterfeit and imitation authorities for OTC products that physically resemble controlled substances, and through its new drug authority when certain criteria are met regarding those ingredients.

It is true that legal questions about the counterfeit authority are being litigated now, and that there is presently precedent for the use of the imitation authority. Experience may thus reveal the need to consider modifying these authorities in ways we cannot presently ascertain.

Mr. Chairman, that is a summary of my statement. We will be prepared to answer any questions you may have.

Mr. GILMAN. Thank you, Mr. Hile. I am sure there will be some questions.

[The prepared statement of Mr. Hile appears on p. 92.]

Mr. GILMAN. I would like to call Gene Haislip, Deputy Assistant Administrator of the Office of Diversion Control of the Drug Enforcement Administration.

Mr. Haislip, welcome to the committee, we ask that you submit your full testimony for the record, and summarize it for us now, we would certainly be pleased to accept that.

TESTIMONY OF GENE R. HAISLIP, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE

Mr. HAISLIP. Mr. Chairman, thank you for this opportunity to appear before your committee again. As you know, DEA and this committee have a long history of cooperating together and working on the drug problem. I think this has been a very productive exercise for DEA, and for the Nation, and therefore, I am very pleased to be before you again.

I have submitted a statement for the record, and I would like to address some of the concerns that I have voiced in there in an informal fashion, if I may.

Mr. GILMAN. That statement will be made a part of the record.

Mr. HAISLIP. Thank you.

I would like to reemphasize DEA's position with regard to look-alike drugs. The drugs involved, themselves, though not controlled substances, are dangerous when used for the purposes for which they are sold. In addition we feel that the look-alike trade further encourages drug abuse of all kinds, and that it is thoroughly objectionable; it is not a question of regulation; it is a question of eliminating this type of activity altogether.

I have some photographs that illustrate the nature of the look-alike problem, which I will supply to the committee. The preparations at the top are legitimate; the preparations at the bottom are the look-alike preparations. As you can see they are almost identical in every respect. Here is another example. The legitimate preparation is the one in the middle, and those around it, again, virtually identical. We have a number of pictures of this kind.

One of the most common drugs of abuse in the country at the moment is Quaaludes. Pictured here is a legitimate Quaalude tablet, alongside the look-alike preparation. Again, you can see that it would take a very knowledgeable individual to tell the difference.

These photographs will be submitted for the committee's examination.

[The photographs referred to follow:]

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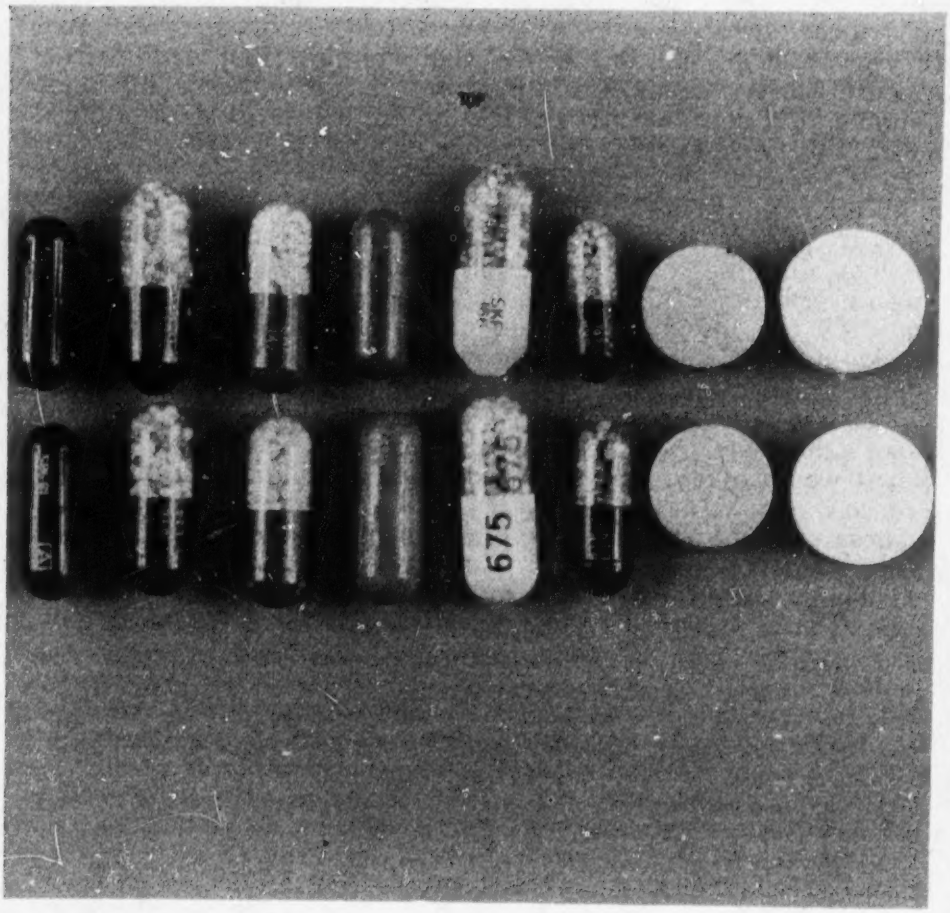

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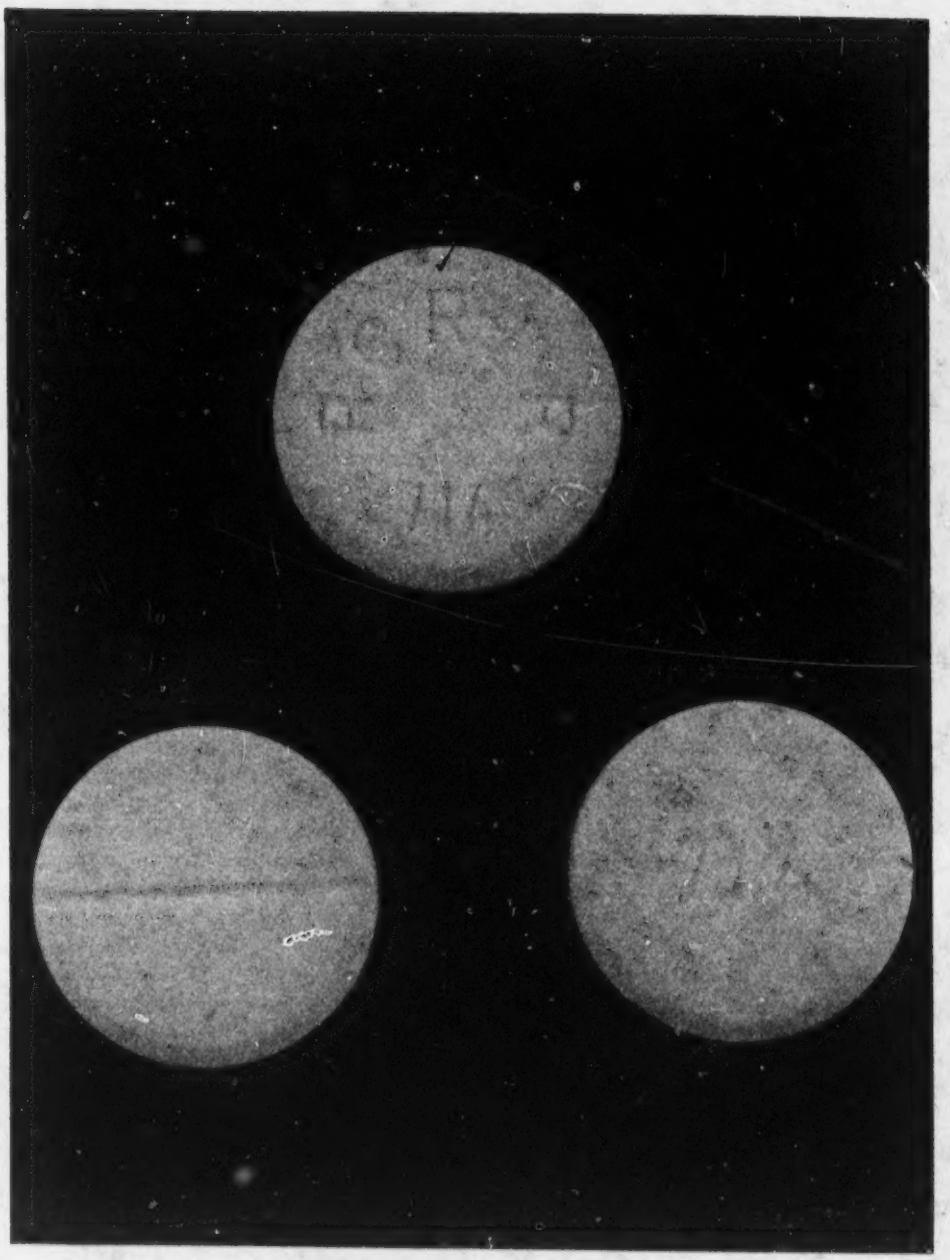

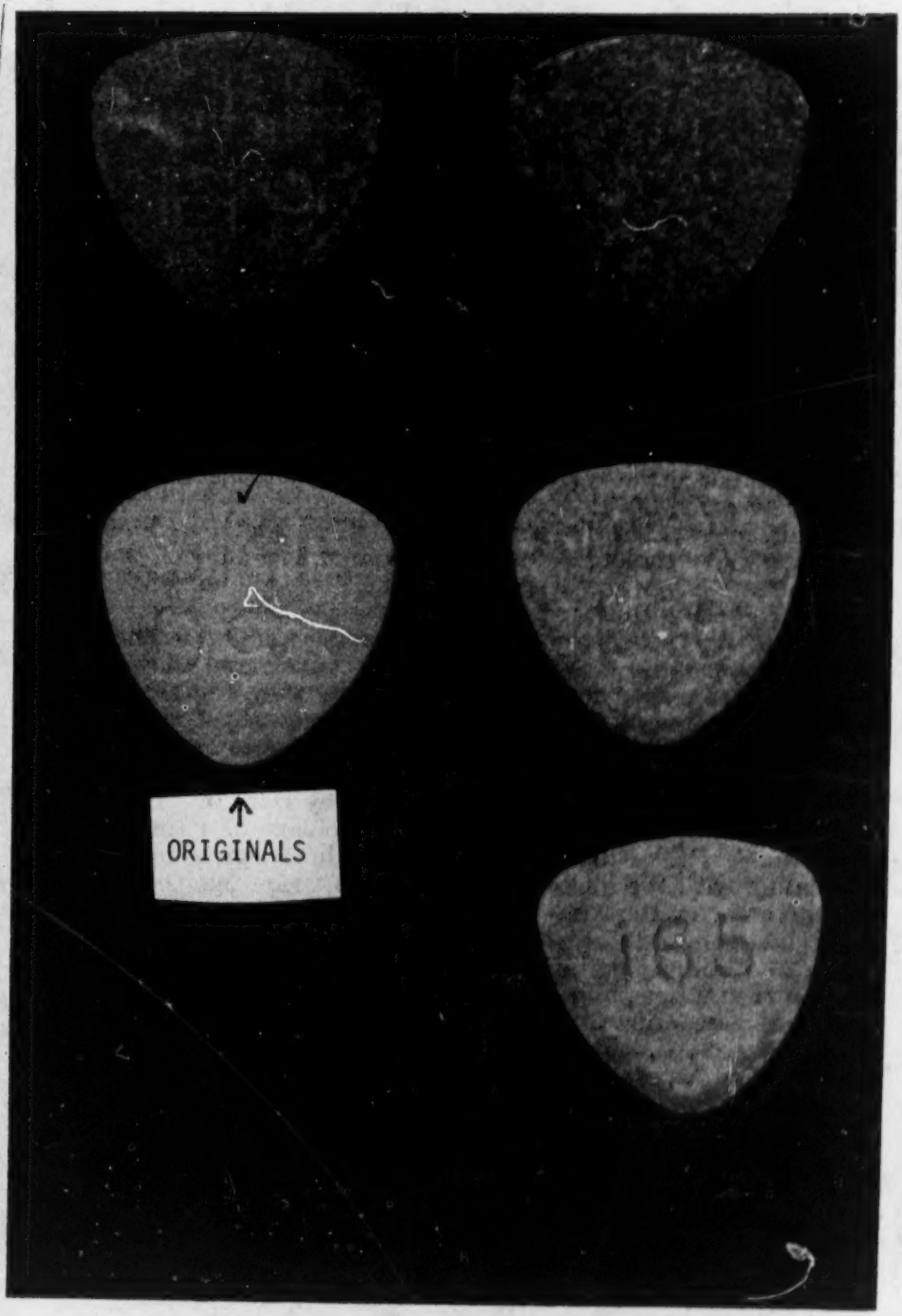
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Mr. HAISLIP. The problem of look-alike drugs burst upon us with some degree of surprise. Neither DEA nor any of the other Federal agencies concerned with the drug abuse problem anticipated or were fully aware of its development, because of the very short period of time in which it evolved.

Nevertheless, I think that we have undertaken a number of actions which in some way have diminished the size of the problem; or have resulted in some modifications or changes in the nature of the problem. In my view, these changes are principally designed to avoid the actions being taken by Federal authorities.

I want to present to the committee what I think is an accurate and balanced picture of where we stand. I am firmly convinced that the measures taken by DEA and other agencies have had a significant salutory impact. However, due to the evasive actions that have been taken by look-alike manufacturers and distributors to continue this enterprise, the problem continues. It is taking new directions, and it is still a very serious problem, which if not addressed, could certainly go beyond even the damage that we have thus far experienced.

I would like to describe some of the actions that DEA has taken to address this problem and suggest some of the changes that have occurred in the nature of the look-alike drug phenomenon. I will also allude briefly to actions taken by other agencies.

At DEA, we viewed this problem as being similar to the one of drug paraphernalia. These are drugs, of course, and they have an extra dimension of danger, but, essentially, they represent efforts by the unscrupulous to profiteer on the drug abuse problem. To engage in the sale of paraphernalia and drugs is to encourage drug abuse.

The States were very successful when they were provided with a model act by which to deal with the problem of paraphernalia. Thus, one of DEA's primary actions was to design a model State act dealing with the look-alike problem, to encourage the States to take action. At the time we undertook this, approximately 11 States had some kind of legislation dealing with this problem. At the present time, 30 States have enacted bills similar to DEA's model and another 15 States have such legislation pending. I think this shows, one, a great deal of responsibility at the State level; and two, the success that this kind of effort can have.

The second aspect of DEA's effort was to help organize and galvanize the actions of the Federal agencies concerned by calling together representatives of those agencies having some responsibility or jurisdiction which could be used to combat the look-alike drug problem. Our purpose in meeting was to coordinate our actions, exchange information, and explore ways to effectively direct our resources to this area. We did this prior to the hearings that were held in October 1981, and we have continued to meet together on a number of occasions, both at the working level, and at the policy level.

A third thing that we did was to solicit the cooperation of the capsule manufacturers in this area, because so many of the look-alikes are capsule type preparations. There are three major capsule manufacturers in the United States and you have heard from one of those this morning. We can all be pleased that these manufac-

turers have undertaken some form of responsible action to deal with this problem, simply because they were asked by the Federal Government to voluntarily examine this issue and respond to it. Their action is an important ingredient to the effort that has been undertaken.

The fourth measure we undertook was to galvanize the public interest by addressing the interest groups, such as the American Medical Association, various drug manufacturers, and action groups in the community who are concerned with drug abuse, to obtain their support for action at the local level. This too has had a salutory effect.

Recently, we have seen that one effect of our action has been to change the nature of the problem, to skew it away from the look-alike problem into other areas. We now see an effort to market other kinds of substances which we have called here the non-look-alike look-alikes.

For example, as you can see here, this is an advertisement for something which is called cocaine. It is not, in fact, we believe, actually cocaine, which is a controlled substance, but probably one of the local anesthetics, such as Lidocaine or Procaine. But, again, it is being advertised as though it were cocaine. You can see here the young lady who is about to snort this preparation--but it says at the bottom, by the way, "not intended for human consumption."

Mr. ZEFERETTI [presiding]. Would you like to pass that up here, please?

Mr. HAISLIP. Yes, of course.

[The photograph referred to follows:]

It's A Real Novelty

COCAINE

If you're in **"THE CROWD"** and need just a little something extra to impress the ladies (or gentlemen) in these times of inflation, just show off your stash of CHATTANOOGA TOOT-TOOT. Its authenticity in appearance and aroma will go unchallenged by even the most scrupulous **connoisseur**. Believe us — if your cocaine looks good, our CHATTANOOGA TOOT-TOOT NOVELTY COCAINE will look better.

Perfect novelty for parties and old fashion head gatherings. CHATTANOOGA TOOT-TOOT NOVELTY COCAINE will make you the life of any party, generating conversation to **last** and **stimulate** everyone throughout the night.

Mixed for perfection with a secret formula paralleled only by the formula for cocaine. We know it has the appearance and aroma similar to cocaine but the difference is **it's 100% legal**.

To order your CHATTANOOGA TOOT-TOOT NOVELTY COCAINE simply fill out order blank on reverse, or to save time and get immediate shipment call our office. We're open from 10:00 a.m. till 10:00 p.m. Monday through Saturday. Let your good **taste** show — order today. Call now! Dealer inquiries invited. Think of it as white gold.
1-615-870-8616, Ext.401

Not intended for human consumption

Mr. HAISLIP. This shows the new direction this market is taking. It shows that, although we have, I think, responded responsibly and energetically, we have not solved the problem.

From what I have said, you can see that DEA's role in this has been critical but limited. Other agencies of the Federal Government, possessing more direct, relevant legislative capabilities, have also forcefully addressed this problem. The Food and Drug Administration has undertaken some very significant actions against manufacturers, and the Postal Service, very early, has taken action against look-alike distributors. These are enforcement initiatives for which these agencies deserve to be commended.

I think it is important to review where we stand and see where we are to go from here. Among other things, we perhaps have not exhausted the capability of the Federal Government to respond within the authorities it possesses. One of the things that needs to be done is to see if there are other agencies which can contribute to the solution of the look-alike problem. It is not clear that all available avenues have been exhausted. Possibly, the Federal Trade Commission may have a role to play, and of course, we have a witness today from there who can address that. After we have, in fact, used all the tools that we possess, then it would be the appropriate time to examine whether additional tools are required.

There has been a great deal of concern over the need for Federal legislation, and what I can say to that today is simply that we have done much without it. It may be that such legislation is needed. The case is not yet clear, nor is the type of Federal legislation entirely clear, and here I would like to offer to you for such value as it may have, some more general reflections on the problem we are trying to deal with.

From my own point of view, it would be objectionable to see bubble gum sold in the manner in which they are selling these preparations and drugs. Because it is clearly designed to pander to and encourage drug abuse. So what we are facing here is a type of marketing of substances, whether they are very harmful drugs, less harmful drugs or whether they are simply innocuous substances. It is a marketing problem. It is the fact that some people are trying to profiteer by encouraging this kind of difficulty.

Mr. ZEFERETTI. Could I interrupt you just for a minute? You say that Federal legislation would not be practical in that sense. If you had a Federal statute like those at the State level, which, as you indicate, some 30 States have adopted, what is the problem that you would face in enforcing this statute?

What would that problem——

Mr. HAISLIP. First, again, I am not saying that some Federal legislation could not address this area. What I am saying is that we need experience to make sure that if it is needed, it is the right kind of legislation.

For example, had we earlier, say, last year, enacted legislation dealing with the look-alike problem, we would have missed completely the new development, in which these drugs are not being sold as look-alikes. The important thing is that we need to be sure, if the problem cannot be solved with the existing laws we have, that any proposed legislation addresses the real problem, and not simply the problem of the day.

I don't personally think the real problem is the particular drug or substance. I think the real problem is the manner in which these products are being marketed, the group to whom they are being sold, and the purposes for which their use is being encouraged.

Now, that is a good deal broader than we have heretofore addressed the problem. And that is what I mean. We need to see if legislation is needed, that it is the right kind of comprehensive legislation so that these people cannot end-run the system, because that is what they are attempting now.

Mr. ZEFERETTI. Have you seen or studied any legislation that any State has introduced that could comply with your philosophy of what you think would be the broad kind of coverage necessary to enforce?

Mr. HAISLIP. The model bill that we designed had some aspects of breadth to it. It remains to be seen if they were sufficiently broad. We have had little experience with those. But the experience we have had has indicated success so far.

Mr. ZEFERETTI. You are not answering my question, though. What I am asking you is, have you seen any State statute that is out there now that you could look at, and say this could be enforced by our agency? And that it covers broadly enough the scope that you are testifying to?

Mr. HAISLIP. I think that our agency, or any agency, given the resources and the mandate could enforce such statutes as exists.

Mr. ZEFERETTI. So that is what the bottom line is, though. The bottom line is that if the statute were written, overall, what you are going to need is the priority to go ahead and enforce it, whether it be manpower, whether it be dollars, whether it be equipment, whatever it might be.

Mr. HAISLIP. That is true.

Mr. ZEFERETTI. That is what I am trying to get to.

Mr. HAISLIP. That concludes my remarks. I think you can see that much has been done. The problem persists, but I see the need to address what is the fundamental problem, and not to see it as simply the look-alike problem.

Mr. ZEFERETTI. Thank you very much.

Before we go on to Ms. Pedersen, let me apologize for being away from hearing for a period of time. My other responsibility is serving on the Rules Committee, and we are quite active with the closing of the session before the recess to get through the House the kinds of legislation necessary for us to work with.

So my absence has not been out of trying to avoid this hearing, but it has been out of necessity to attend and vote on other pieces of legislation.

[The prepared statement of Mr. Haislip appears on p. 97.]

Mr. ZEFERETTI. Ms. Pedersen, we welcome you, and you may proceed.

TESTIMONY OF AMANDA B. PEDERSEN, DEPUTY DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION

Ms. PEDERSEN. Thank you, Mr. Chairman.

I am Amanda Pedersen, the Deputy Director of the Bureau of Consumer Protection of the Federal Trade Commission, and I want to thank you for this opportunity to testify on the problem of look-alike drugs.

A written statement has been submitted to you for the record, but I would like to briefly summarize my comments here.

Mr. ZEFERETTI. Fine.

Ms. PEDERSEN. I would like also to note at the outset that these remarks reflect my own views as the Deputy Director of the Bureau of Consumer Protection, and do not reflect official Commission policy.

Mr. ZEFERETTI. Would you please, and excuse me for interrupting you, but would you please outline for the record—because there were some questions earlier in the day, Mr. Hyde and Mr. Railsback—about the inability of your Agency to send a representative that could speak for the agency itself.

Ms. PEDERSEN. Certainly, I would be glad——

Mr. ZEFERETTI. And I would like you to explain that.

Ms. PEDERSEN. Yes, I would be glad to. The Federal Trade Commission is an independent regulatory commission that has, by statute, five commissioners, although there are only four sitting Commissioners now. In order for an official Commission statement to be given, it must be considered, voted upon, and approved by a majority of the Commissioners.

FTC staff has frequently come to testify in congressional hearings. However, in order for a staff member to appear, the staff member must obtain the authorization of a majority of the Commissioners. They, in giving that permission, do look at the statement that will be made, but they do not approve it as an official Commission position.

In order for an official Commission position to be developed, it ordinarily starts with an investigation or other action at the staff level, which works its way up through the management of either of the two operating bureaus—the Bureau of Consumer Protection or the Bureau of Competition—and then is presented to the Commission for a vote. It becomes an official action or position if approved by a majority of the Commissioners.

An individual Commissioner who testifies in a hearing, also always testifies as an individual Commissioner, unless a vote has been taken beforehand on the particular issue.

Mr. ZEFERETTI. Isn't there a policy that you could follow that is an overall policy of the entire Commission that you could report to us on, on a particular issue?

Ms. PEDERSEN. In this particular case, of look-alike drugs, there is no overall policy on this subject. What we have, and what I think has been made available to your committee is a staff recommendation for an investigation in this area which represents the starting point of the process, rather than the finishing point. This recommendation must be reviewed by bureau management before forwarding to the Commission. Thus, it is on its way to the Commission, but it has not gotten there yet.

Mr. ZEFERETTI. OK, you may proceed. I just wanted to make that part of the record, so that that explanation could be available for the rest of the members of the committee.

Ms. PEDERSEN. The problem of look-alike drugs continues to be of grave concern to us. The growth of this trade is especially troubling as it appears to be successfully targeted to young people. Current figures available to us also indicate that the health hazards associated with the use of look-alike drugs are significant.

Previous hearings of this committee focused attention on the serious nature of this problem. Since that time, the FTC staff has participated in an interagency task force, with representatives of the FDA, the DEA, the IRS and the Postal Service to share information and to develop strategies.

In my view, drug abuse through the use of look-alikes is not primarily an advertising or marketing problem. The fundamental problem with look-alikes, if these drugs are as harmful as we understand them to be, is that they are manufactured and sold at all.

The questions thus raised may not be best resolved by the Federal Trade Commission. As indicated in my written statement, the Commission's authority to prohibit deceptive advertising may not be applicable here.

However, we are presently reviewing a staff recommendation for a full-phase investigation under the FTC's unfairness authority. As you know, the Commission's articulation of its unfairness authority requires three criteria to be met before a violation exists.

The development of these criteria came in response to a congressional request in 1980, and was developed in connection with a significant review of Commission authority, and presented to the Congress. However, the standards for meeting three criteria are still developing.

We will be examining these issues and other issues in detail before making a final recommendation to the Commission. I am most seriously concerned about the FTC's ability to mandate a timely and effective remedy.

A product ban may be the only meaningful remedy, but it is unclear whether the Commission's authority provides for such relief.

[Note: In November 1982, the committee was advised that a full-phase investigation of the look-like industry had been authorized to study the issue of whether the FTC has jurisdiction in this area, and if so, whether FTC can impose an effective remedy.]

While there are, therefore, many questions regarding the Commission's direct intervention, the staff is encouraged by Warner-Lambert's recent proposal to require purchasers to enter a continuing guarantee not to use capsules for the production of look-alike substances.

Because of the real benefits that might result from such a program, we would be pleased to work with this committee and the manufacturing companies regarding such proposals and in particular, to avoid potentially serious antitrust problems.

Mr. Chairman, these problems were outlined by us in a letter to this committee in late July, signed by the Directors of both the Bureau of Competition and the Bureau of Consumer Protection. I would like to have that included in the record, if I may.

Mr. ZEFERETTI. Without objection.

[The letter referred to appears on p. 88.]

Ms. PEDERSEN. Thank you.

In conclusion, let me emphasize my deep concern about the look-alike problem. We will continue to evaluate the opportunities for

action, and to work with other State and Federal agencies. We also encourage continued efforts by industry and reiterate our willingness to cooperate.

I want to thank you for inviting me to testify, and at the appropriate time, I would be pleased to answer any questions.

Mr. ZEFERETTI. Thank you.

[The prepared statement of Ms. Pedersen appears on p. 100.]

Mr. ZEFERETTI. Mr. Madden?

TESTIMONY OF DAVID W. MADDEN, POSTAL INSPECTOR IN CHARGE, CINCINNATI, OHIO, DIVISION, U.S. POSTAL INSPECTION SERVICE, U.S. POSTAL SERVICE

Mr. MADDEN. Thank you, Mr. Chairman.

I, too, thank you for the opportunity to appear here today. I have a short statement, which I will read.

Mr. Chairman, my name is David W. Madden, and I am the Postal Inspector in charge of the Cincinnati Division of the Postal Inspection Service. Formerly, I was the Postal Inspector in charge of the Special Investigations Division, which conducts the investigations of mail order sales of look-alike drugs.

On October 26, 1981, former Assistant Chief Postal Inspector William T. Murphy and I testified at your hearing in Jersey City, N.J., on the Postal Service's efforts to curtail the mail order sale and distribution of look-alike drugs. Today, I would like to provide you with the status of our efforts.

During our testimony on October 26, we mentioned that the Postal Service had filed false representation complaints under title 39, United States Code, section 3005, against 11 companies who were using the U.S. mail to sell look-alike drugs.

These companies ceased their mail order operations as a result of consent agreements or false representation orders which directed the return of their mail to the sender. Since that hearing, the Postal Service has filed false representation complaints against 30 additional companies. These companies have also ceased the mail order sale of look-alike drugs.

Recently, we completed investigations relating to 18 other companies which are promoting the mail order sale and distribution of look-alike drugs. These cases have been presented to the Postal Service Law Department to consider whether false representation complaints should be filed.

The sale and distribution of look-alike drugs by mail order appear to have been curtailed as a result of the civil enforcement actions which I have mentioned. Nevertheless, most of the major promoters are circumventing the false representation orders and consent agreements by continuing their activities outside the mails.

Their current advertisements tell prospective customers that only telephone orders will be accepted and that payment must be by credit card, bank wire, or United Parcel Service C.O.D. These procedures remove the orders and the money from the U.S. mail, thereby rendering any mail stop order remedy under current law ineffective.

We will continue to investigate any company seeking orders or money from false and misleading advertisements of look-alike

drugs. However, to the extent that they are able to distribute their products and receive moneys outside the mails, then their activities are beyond the administrative authority of the Postal Service to deal with them.

The bill, S. 1407, which has passed the Senate and is now pending in the House, would seek to deal with this kind of situation by authorizing the Government to seek civil penalties in court against anyone who resumes a false representation scheme in interstate commerce but outside the mails after a valid mail stop order has been issued.

I might comment that we testified on H.R. 3973, which includes those provisions on July 22.

We are often asked whether look-alike drugs are safe to use. Information received from other law enforcement officials, public officials, and the news media, both television and newspapers, has attributed at least 16 deaths, by our count, and 1 case of paralysis to the use of these drugs.

Expert testimony obtained by the Postal Service for its administrative enforcement actions has shown that look-alike drugs are a serious safety and health hazard. The full potential of the adverse effects caused by the combination of caffeine, PPA, and ephedrine has never been established.

Based on this expert testimony, the Postal Service has included the safety and health hazards of the products in the false representation complaints filed against the promoters of look-alike drugs.

At the request of your staff, we have made a preliminary review of Senate bills S. 2735 and S. 2736. Senate bill 2735 proposes an amendment to title 39, United States Code, section 3001. The amendment, in essence, would make any matter which reasonably could be interpreted or construed as a drug-abuse advertisement or a shipment of imitation controlled substances in response to such advertisement nonmailable for the purposes of the administrative remedies administered by the Postal Service.

Senate bill 2736 would make the manufacture or distribution of imitation controlled substances, except for authorized purposes, a criminal offense.

The Postal Service has not yet had sufficient time to complete its review of this legislation, which was introduced in July.

Mr. Chairman, I want to thank you for the opportunity to appear before this committee, and I would be happy to answer any questions you have.

[The prepared statement of Mr. Madden appears on p. 102.]

Mr. ZEFERETTI. Thank you very much.

Let me start, I think, as a panel discussion, anyway. One of the things we have is a difference of opinion between the Drug Enforcement Administration, and your agency, Ms. Pedersen, in how we should go about solving this whole problem of look-alike drugs.

And in looking at your statement, and if I just may read a paragraph on page 3:

> Even if the FTC successfully brought a deceptive advertising case, the impact would be limited. If the Commission were able to prohibit all advertising, the most likely result would be that sellers would simply alter their method of marketing. If it were able to prevent specific claims, sellers would easily change their advertisements.

Finally, if disclosures were mandated regarding health hazards or illegality, it would probably have little effect in determining the purchases. It might even enhance the desirability of the products.

That is in complete conflict with what Mr. Haislip was saying from DEA. And just for the sake of getting some discussion started as to which way is the best way for us to proceed, I would like the both of you to comment, and beyond that, we know that your Department has made an investigation, and it has been active, and it has been a long time coming.

We are hoping today that you might tell us that we are going to have some kind of information forthcoming in the very near future. I would hope that that would be a reality for us, but I would like the two of you to comment on what was just——

Ms. PEDERSEN. OK, let me answer the last question first. The recommendation that you have is a nonpublic staff paper. And it presents—it touches on the two central problems: First, does the Federal Trade Commission have jurisdiction to act in this matter; and second, can we mandate a timely and effective remedy to deal with the problem?

On the jurisdictional point, that memorandum is a staff memorandum that has not been approved by the Bureau. One of the areas that we are seriously looking at, which I touched on in my testimony, is that memorandum does not discuss the unfairness jurisdiction as delineated by the Commission in response to Congressional action. And, as you may know, this definition of unfairness is now included in our pending reauthorization legislation.

Thus, the process of defining the Commission's unfairness jurisdiction began in 1980, and continues. However, the Commission has an unfairness protocol; it has an enforcement statement that was originated because of congressional request, and we must operate under that. The legal analysis in that memorandum does not take that into account, and therefore, whether we have jurisdiction over the problem of look-alike drugs is a very difficult question, and it is one we will be very seriously considering.

The second point is, even if we have jurisdiction, can we mandate a timely and effective remedy. The memorandum, as you may recall, outlines the four tiers of the industry, and suggests, because of the number of wholesalers and retailers at the third and fourth level, that the only hope of taking any effective action would be at the first and second tiers. The first tier being Warner-Lambert and the manufacturers of the capsules; the second tier being the encapsulators and the tableters.

There are significant legal questions as to the reasoning in that staff memorandum regarding reaching Warner-Lambert or other manufacturers because their products were subsequently used in the look-alike trade. I think that Warner-Lambert's proposal is a very responsible way to deal with the use of their capsules in this trade, and I don't think the Commission would have jurisdiction to reach back to hold Warner-Lambert liable.

In terms of the second tier, whether we have jurisdiction over that tier, that is the encapsulators and the tableters, and whether there is any effective remedy, if we had jurisdiction, we could impose, are the two questions that we will be focusing on.

And the answers to those questions, I would hope, would be forthcoming fairly soon. Part of the answer does, obviously, depend on a certain amount of factual development, particularly in terms of whether or not there is an effective remedy. For example, we don't have enough information at the moment about tableting, the processes that are used, where the raw ingredients come from. Obviously, capsules are very hard to come by. By contrast, tablets are easy to make in terms of mechanical equipment.

These are the serious concerns that we are looking at, and in terms of why we don't think it is a marketing problem, I think that is my shorthand way of saying we, as an agency, even if we had jurisdiction, cannot deal with the multiplicity of wholesalers and retailers across the country. As the attorney general from the State of Illinois was saying this morning, that if he shuts them down in Illinois, they pack their bags, change their name, and go into another State.

And I think as a practical matter, that is beyond the capability——

Mr. ZEFERETTI. If we provided a Federal statute that would limit the accessibility of that kind of advertisement, wouldn't that make it enforceable as far as——

Ms. PEDERSEN. I would have to look very carefully at the statute, because again, as the State attorney general said this morning, whenever you get into prohibiting advertisements absolutely, you have first amendment problems.

One of the other points I think I should make here is that under the unfairness jurisdiction, which is the jurisdiction that is discussed in this staff proposal, the FTC is prohibited by statute from engaging in any rulemaking in advertising. The FTC still has jurisdiction to go on a case-by-case basis, but the 1980 FTC Improvement Acts prohibited the Agency from engaging in any rulemaking in advertising based on the unfairness jurisdiction.

The look-alike drugs ads, by and large, do not appear on national or regional television, or in major publications the kind of ads that we usually monitor. Rather, the few look-alike drug ads that I have seen were back-of-the-book ads, or in more local publications.

That is the kind of situation that we might approach by rulemaking, but we are now by statute prohibited from engaging in rulemaking in advertising under the unfairness jurisdiction.

Mr. ZEFERETTI. Mr. Haislip, what is your point of view, vis-a-vis the advertisement and marketing aspect?

Mr. HAISLIP. Yes, if I may reply to your question. First of all, I am unable to make comments about the capabilities of the FTC in dealing with the problem. I am not familiar with their legislation, and do not know what is possible to be done by that agency with their existing law. I hope you haven't understood me to suggest anything to the contrary. Though I think that law needs to be explored to see if the matter can be dealt with, even in a partial fashion. I don't want to comment on FTC authority or legislation. I simply am ignorant about that.

I would like to comment on the nature of the problem, and why I refer to it as a marketing problem. I think it is a marketing problem, because it is the reason for which these substances are being sold that is objectionable, not simply the substances themselves.

If any drug preparation, let us say aspirin, was packaged and sold with the suggestion that it was for abuse and that it had those kinds of effects, I would find that objectionable, and I think that is really the crux of the problem.

The drugs themselves that have been used are dangerous, but they are not sufficiently habit forming or sufficiently debilitating that they can be controlled as controlled substances. They have avoided that particular restriction. They are nonprescription drugs. Now, in the case of a nonprescription drug, an over-the-counter drug, we may be faced with a situation in which there is so much abuse of a nonprescription drug that it needs to be taken off of that status and made a prescription drug.

That is a problem that Dr. Pollin has alluded to in the case of diet preparations. But here we are dealing with a nonprescription drug which is being marketed explicitly for abuse, not for any legitimate purposes, only for abuse.

Mr. ZEFERETTI. As you indicated with this here. This is a perfect example of what we are talking about.

Mr. HAISLIP. That is right. So I don't even think that presents a gray area. My fear is that if we approach the problem as a substance problem, dealing first with ephedrine; secondly with phenylpropanolamine, what we are going to finally do is to find out we are dealing with aspirin and sugar and everything else. And we will never have really dealt with what is the fundamental problem. That is why I have referred to it as a marketing problem. But it is correct that sometimes the manner in which these preparations are advertised is not deceptive. They do have some of the effects that are claimed.

It is not a case of deception. It is just a case of an obnoxious, unwanted, harmful practice. Now, that is why I want to separate my point of view from being a specific comment on what may or may not be the authority of the FTC, of which I am essentially ignorant.

Mr. ZEFERETTI. Before I turn it over to Mr. Gilman let me ask Mr. Hile a question. Your Agency, the FDA, has successfully made some seizures of look-alike drugs.

Mr. HILE. Yes, sir.

Mr. ZEFERETTI. By what authority were those seizures made?

Mr. HILE. Original seizures, Mr. Chairman, were under the counterfeit authorities of the Food, Drug, and Cosmetic Act. Those authorities provide for the seizure of the tablets, associated raw materials, containers and the equipment used to manufacture counterfeit drugs.

Mr. ZEFERETTI. Were those manufacturers or distributors seriously affected? Was there any kind of a follow-up or a monitoring of those agencies—of those industries, I should say?

Mr. HILE. Yes, sir, there was. We have, as a consequence of the seizures, been in litigation with those firms. Five of the firms have entered into consent decrees. Most of those decrees include injunctive provisions which prohibit their manufacture of counterfeit drugs and imitation drugs.

Also, the court orders for those decrees called for the destruction of all finished dosage forms that we seized, the empty capsules, the dyes and the other equipment used to manufacture—specifically to manufacture the counterfeit drugs.

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There are four firms remaining, and we are actively pursuing consent decrees on those cases.

Mr. ZEFERETTI. Are you putting forth any regulatory changes? Are you making any regulatory changes to enhance your ability to go after some of these people?

Mr. HILE. Yes, sir, we are. Our monitoring of the OTC look-alike problem generally, and our monitoring of the activities of the nine firms, specifically, began to reveal to us that a number of the firms were departing from the manufacture of strictly counterfeit drugs or even imitation drugs, and believing they had established a marketplace for the drug product itself, were actively engaged in manufacturing drug products that were not literally counterfeit or imitation, but contained the drug ingredients which had been involved in the OTC look-alikes all along, particularly drug products containing all three, phenylpropanolamine, caffeine, and ephedrine.

That information was supported by other kinds of information coming to us from DEA and NIDA and elsewhere. We undertook an inquiry of our own, and have, as a consequence of that, concluded that the so-called triple combination of those three drugs has no status as an approved drug, and have concluded that it is a new drug being marketed without benefit of approved new drug application.

We have undertaken an investigation of all of the known manufacturers of look-alike drugs and others that are, we suspect of manufacturing these kinds of drugs, and in each instance, have officially notified them through a regulatory letter, which is an official administrative process, that those drugs are new drugs, and cannot be marketed without benefit of new drug application.

In 10 instances, the firms have advised us that they intend or have discontinued the manufacture of those products. We will monitor that commitment and certainly to the extent that it is not adhered to, we will use the civil sanctions that are available to us, seizure and injunction, to assure that those products are not manufactured and distributed.

Mr. ZEFERETTI. Thank you.

Mr. Gilman?

Mr. GILMAN. Thank you, Mr. Chairman.

Mr. Haislip, there was a Washington Post article back on June 30 that quoted you as expressing concern about the illegal importation of methaqualone and the Quaaludes that were being manufactured here were based on an illegal importation coming in directly from China.

Is there a problem with regard to the look-alikes being manufactured in foreign countries, and is there no legal importation of the look-alikes, and what is the situation with regard to this Quaalude substance?

Mr. HAISLIP. Well, I would like to address each part of that question. That particular article references the problem of methaqualone, or Quaaludes, which has been one of the fastest-growing drug abuse problems in the country.

We discovered that virtually all of this material was coming from foreign sources. We have worked with most of those countries, and now, the People's Republic of China is the only major source of supply for methaqualone in the illicit traffic.

Virtually all of the material coming into the United States illegally is of Chinese manufacture, and unfortunately, the Chinese have not been interested in speaking with us about that problem, so we have not been able to shut that source off as we have in the case of several other European countries. Perhaps in excess of 40 tons of methaqualone is entering the United States illegally through other countries, which is of Chinese manufacture. We have sought to make this known to the Chinese Government through our Embassy in Beijing.

Mr. GILMAN. You have estimated the total sales of that substance would be about $2 billion annually; is that correct?

Mr. HAISLIP. That is correct, Congressman. I think it is one of the largest drug problems we have to deal with. The amount of death and debilitation associated with it is essentially equal to that associated with heroin.

Mr. GILMAN. Does that get into the look-alike problem?

Mr. HAISLIP. Well, I think the relevance is this: These Quaaludes are not look-alikes but counterfeits. There are, however, genuine counterfeits. The other relevance we have found the control actions we take in our country will not be effective in the long run if something is not done in the international area.

Now, you heard this morning from Warner-Lambert that indeed there is an effort to seek capsules for look-alikes from overseas sources. And in this sense, it is a similar type of problem. But I think where we can gather the evidence and where the governments are willing to entertain the evidence, we can in time shut those sources off.

That has not always been possible at this point, so far, it has not been possible in the case of methaqualone, but of course, those efforts are still under way.

Mr. GILMAN. And where we have foreign exports of this kind of substance, then the DEA does have some jurisdiction, does it not?

Mr. HAISLIP. We have some jurisdiction, and we also have some special capability because of the fact that we maintain personnel around the world. There are limits, but there is much that we can do in a case of that kind.

Mr. GILMAN. I am concerned in listening to all this testimony, that there is an apparent lack of stringent enforcement provisions in the entire issue of look-alike drugs. We can enjoin and we can prevent the manufacturers from proceeding to manufacture the product, but apparently there is very little by way of enforcement at the Federal level. Is that correct? By way of a criminal penalty.

Mr. HAISLIP. Most of the enforcement actions that the Federal Government has undertaken in this area have been undertaken by the FDA and the Postal Service. What all of us here from the Federal agencies have been attempting to do is to respond to a novel problem that suddenly exploded on the scene quite unexpectedly, that none of our laws has really been designed to deal with, to respond to it through the authorities that we had in the hope that we could knock this business out in the fastest and shortest possible timeframe, and I don't think any of us know if we can succeed in that with our existing authorities.

Mr. GILMAN. Is that the purpose of your task force on the look-alike problem?

Mr. HAISLIP. Yes, Congressman.

Mr. GILMAN. When was that task force established?

Mr. HAISLIP. We established it informally, that is to say, we met together for the first time in the spring of 1981, but since the hearings of this committee, it was formally instituted and it has met—since the last hearings, it has met both at the working level and the principles level on, I think, four or five occasions, more than quarterly.

Mr. GILMAN. Well, this problem certainly hasn't come up overnight. And last year, our committee conducted extensive hearings on the look-alike problem, and many of you appeared before our committee.

And at that time, there was a recognition that there was a need for more stringent provisions by way of enforcement remedies.

What has been done in all that period of time? You have got a task force at work; there has been a recognition of the problem. It has been over a year now since we last met together. What is the problem with regard to providing some more effective criminal penalties in this area?

Mr. HAISLIP. I think that, and each member can address this for his own agency, but I think that effective actions have been undertaken by those who are before you. It is a question of whether they will be sufficient or adequate.

Mr. GILMAN. Well, do you feel that it is sufficient?

Mr. HAISLIP. At this point, they have certainly not solved the problem. They have somewhat changed the nature of it, and in certain areas reduced it.

Mr. GILMAN. What do you think should be done now to make it more effective and more efficient, and be able to get a handle on the problem?

Mr. HAISLIP. If the actions that we have undertaken, and if the passage of the DEA model State act is successful in dealing with the problem, that could be sufficient. If not, then obviously you are going to have to look at both the legislative and resource question.

Mr. GILMAN. You heard testimony today from Attorney General Fahner of Illinois, who said that there is certainly a strong need for Federal legislation, and you are telling our committee now that the model State act would suffice.

Do you agree with the Attorney General that there is a need, or can we depend wholly upon the State enactments?

Mr. HAISLIP. No, Congressman, I would hope the model State act would suffice, but it may not, and that needs to be evaluated. If it is not, then Federal legislation would be necessary.

Mr. ZEFERETTI. If my colleague would yield, I don't know how long we are going to have to wait. If the Federal agencies themselves that have jurisdiction can't act quickly upon this particular problem, then I don't know how we are going to ever have the ability to evaluate what is to go forward, and I think that is the crux of the problem, we have not acted quickly enough to get that kind of response, and I am sorry for that.

Mr. GILMAN. I thank the chairman for his comment.

I am curious, Mr. Haislip, just where the task force is at this moment. What have you recommended, then, to correct the problem and to improve the situation?

Mr. HAISLIP. What we have attempted to do in the task force is to explore the existing abilities of each agency to undertake action based on the legislation we have. The second thing we have done is to exchange information with regard to the problems we had to deal with and information at the operational level.

We have tried to make sure that we squeeze the most action out of the authority and resources we currently possessed. We have not formulated recommendations beyond that point.

Mr. GILMAN. But it is obvious from the testimony we have heard that those abilities are limited, and that there is a need for more than the present capability, and what I am curious about is what is the task force doing to improve that capability, to stem the flow of these look-alike drugs that are flooding our markets?

Mr. HAISLIP. We have not examined or tried to make recommendations with regard to the need for new legislation. That is not the area that we have addressed. We have tried to address the operational problem before us and to do as much as we could with what we have.

Mr. GILMAN. Well, if the task force sees a need for a new remedy or a new vehicle, I would assume that you would make some recommendation to the administration and to the Congress? Isn't that correct?

Mr. HAISLIP. I think that would be responsible, yes.

Mr. GILMAN. Will there be some recommendations forthcoming from the task force in that direction?

Mr. HAISLIP. I am unable to say.

Mr. GILMAN. Who chairs the task force?

Mr. HAISLIP. Congressman, I chair the task force, but remember that this is simply a voluntary coming together to try to insure that Federal activities are coordinated. This is not a compulsory task force that——

Mr. GILMAN. Who comprises the membership of this task force?

Mr. HAISLIP. The agencies that are represented here plus the IRS attends, as well; NIDA also has begun attendance. We have tried to include all of those who could have a role, and obviously some of us have been much more active than others.

Mr. GILMAN. Does this task force meet with Dr. Carlton Turner, the White House Adviser on Narcotics?

Mr. HAISLIP. It has not.

Mr. GILMAN. Has it made any recommendations to Dr. Turner?

Mr. HAISLIP. No, there have not been.

Mr. GILMAN. Do you intend to make some recommendations?

Mr. HAISLIP. That is a question that we are going to examine on our next meeting.

Mr. GILMAN. Well, it is obvious that there is certainly a need to do a lot more than we are doing, and it is certainly obvious that there is a need for some better remedies than we have available, and I would hope that this task force, with all its expertise and all of its front-line field people who are out there doing the work, could come up with some worthwhile recommendations for both the Congress and the administration, so that we can make your work a lot more effective and accomplish a worthy result.

I would hope that we would see some sort of a recommendation of that nature in the near future.

Thank you, Mr. Chairman. I thank the panel, unless some of the other panelists would care to comment.

Mr. Hile?

Mr. HILE. Mr. Gilman, I would just like to make a comment or two. Your frustration, of course, is shared by the members of the task force, not over the activities of the task force as much as what are the appropriate solutions to this evolving problem.

I think I can speak for all of us in that when this problem first began to emerge, our initial strategies were to move, under our current statutes, to disrupt the manufacturing of these products, and to try and remove them from the marketplace.

These activities were taken under administrative and civil sanctions. This does not preclude the consideration on the part of the involved agencies, and particularly the Food and Drug Administration, of possible criminal actions, but certainly, in a sequence of regulatory action, that is of second importance to us.

Our first focus is to try and disrupt the manufacture of the product, and remove lots of products from the marketplace.

Second, I think we all have approached this matter under a philosophy that agencies collectively or individually can be most credible in coming to the Congress asking for additional legislation if it can be demonstrated that the authority of the current legislation has been exhausted. And certainly, we are actively pursuing those kinds of activities now.

Third, the third point I would like to make is that we have been dealing with what is an evolving issue, and has presented, in a sense, a moving target for us. And so it has been difficult for us to focus specifically on what might be appropriate remedies if those remedies are necessary in addition to the current statute.

I think we are all committed to moving to reach those kinds of decisions as quickly as we possibly can, but at the same time, focus our energies and efforts and resources on trying to do something with the problem right at this moment in time.

So it has been a difficult effort, but a continuing one for us, and we are all committed to positive actions as a consequence of our activities.

Mr. GILMAN. Has there been any successful criminal prosecutions of any of the manufacturers of look-alike drugs?

Mr. HILE. Not under the Federal Food, Drug, and Cosmetic Act. That would be a consideration in our strategy, after having moved to focus on the manufacturing of the product which is our first focus, to see if we can interrupt the manufacturing of the product and its distribution.

Mr. GILMAN. Mr. Haislip, do you know of any successful criminal prosecutions?

Mr. HAISLIP. I do not.

Mr. GILMAN. Ms. Pedersen?

Ms. PEDERSEN. I do not.

Mr. GILMAN. Mr. Madden?

Mr. MADDEN. No.

Mr. GILMAN. You know, I noticed in your testimony on page 8, you are talking about an excellent example of the successful interagency cooperation, and how you put the Frye pharmaceutical

business out of business, and yet Frye continues to manufacture elsewhere.

And now, you are talking about holding them in contempt of court, but there isn't any criminal penalty for all of this. And here is a person and a company that continues to manufacture and supply these look-alikes to the youth of our Nation, and we in the Federal Government slap them on the wrist.

It seems to me that a lot more should be required in a situation of this nature, and a lot more could be done by the Federal agencies, a lot more could be done by the Congress working with the Federal agencies if you will point out where the need is.

I think we, by this hearing, pointed out some needs, and I am sure that some of us in the Congress will try address some of those needs.

But I would hope that your task force would come up with some worthwhile recommendations in that direction. Do any of the other panelists wish to comment?

If not, I want to thank you, Mr. Chairman.

Mr. ZEFERETTI. Thank you, Mr. Gilman.

My last comment, it is my understanding that—and I wasn't here at the time—in his testimony, Dr. Pollin made reference to the fact that NIDA has instituted a task force that is working with all of you, I believe, and that is developing a strategy, if you will, that would attack this whole look-alike problem.

Have you all played an integral role in that task force, also?

Mr. HAISLIP. I think that he is referring to a strategy for information collection rather than an operational strategy to deal with the persons who are engaging in this activity.

Mr. ZEFERETTI. I would hope that in your next meeting that you would put on your agenda some analysis and discussion of Federal legislation or a statute that might enhance this fight against the look-alike problem.

Mr. HAISLIP. I think with what you have said, what Congressman Gilman has said, we will certainly have to do that. Again, I emphasize our task force is a voluntary coming together, our task force, and each agency does have its separate responsibilities to its parent Department. But we will certainly do as you have indicated.

Mr. ZEFERETTI. Since the problem is getting bigger, I would suggest that maybe this voluntary group should meet in a little bit more hasty fashion, so that we could address this problem before it mushrooms into a larger problem and affects a lot more young people in our society.

Again, I want to thank you all for appearing here. We appreciate the appearance of all the witnesses today. This is a very, very difficult problem, and we would hope that all the Federal agencies and all parties concerned will move quickly to help us formulate a policy that could combat this look-alike problem. We are here to work with you in any way that you think we may aid in that effort. We thank you once again. This will conclude our meeting for today.

[Whereupon, at 1:10 p.m., the select committee was adjourned.]

PREPARED STATEMENT OF TYRONE FAHNER, ATTORNEY GENERAL, STATE OF ILLINOIS

Chairman Zeferetti, Congressmen Railsback and Hyde, and distinguished members of the committee, thank you for allowing me the opportunity to testify before you today on a very serious topic * * * the spreading epidemic of "look-alike" drugs that has swept our country almost uncontrolled.

We are faced with a serious drug problem in America that many of us didn't even know existed a few years ago. I would even venture to say that the growth of "look-alike" drugs has been the fastest developing drug problem in the country, and perhaps the most deadly.

We know of at least seven deaths in Illinois attributable to the use of "look-alikes" over the past year and a half. I say "We know of about seven deaths," because some parts of the State—including the city of Chicago—do not keep records on drug overdose deaths that differentiate between deaths due to controlled and non-controlled substances. Some authorities suggest that well over a dozen young people have died in Illinois due to "look-alike" drugs.

Surprisingly, there have been more deaths linked to "look-alikes" than real amphetamines in Illinois. And, this is a fact I find astounding. We estimate that in 1981, 15 times more "look-alikes" were being manufactured in this country than amphetamines. Before June 1981, 1.7 billion doses of "look-alikes" were produced each year. That means eight "look-alike" tablets or capsules for every man, woman and child in America.

Those are frightening statistics. They are even more so when you consider that these drugs are not prohibited by Federal law and are legal in many States, they are manufactured without quality control, and they are being pushed on very young children as "Safe, legal and effective stimulants."

How dangerous are "look-alikes"? Well, one of the people we know to have died in Illinois due to "look-alikes" was a State fair worker. On August 4, 1981, the young lady took just a couple of capsules * * * and she's dead.

Many people in law enforcement believed nothing could be done to restrict these drugs. I received complaints from drug agents, local police and sheriffs, parents and school administrators. I was sympathetic, but without an apparent remedy because no State or Federal criminal law applied, there seemed little we could do.

Then I was given a copy of a pamphlet being distributed on a high school playground in Springfield, Illinois. The pamphlet said "why pay more to an unlicensed street dealer?" the inside offered an assortment of pills and an assurance that the "look-alikes" are "legal, safe, effective and profitable stimulants." You could buy them * * * mail order * * * by the tens of thousands. Other companies even offered free samples by mail.

My staff and I decided something must be done. In May, 1981, we took our first action. We filed suit against R.S.L. Pharmacal of Maryland and three of its owners. That company is now out of business. We alleged violations of the Illinois Consumer Fraud and Deceptive Business Practices Act, the Illinois Deceptive Trade Practices Act and the common law of nuisance.

Over the past 18 months, the number of manufacturers and distributors we've sued has grown to 41 in 15 States.

About two-thirds of the firms we've sued have voluntarily stopped doing business in Illinois or have folded-up or moved elsewhere; and "look-alike" manufacturers admit that the flow of the drugs has dropped from about 30 million tablets and capsules a week to 5 million.

We have no illusions about our success, however. Some companies we have sued and closed have popped up again under a new name and location. And just because we stop a "look-alike" distributor in Illinois doesn't mean we've solved the national problem. Until Congress acts by giving law enforcement authorities a strict, enforceable "look-alike" drug ban, many more young people will die and a group of low life merchants will continue to profit at the expense of our young people.

Many States have already taken up the challenge of stemming the "look-alike" drug problem. In Illinois, we have proposed and passed legislation that we are confident will stop "look-alikes" in our State. That bill is now awaiting the Governor's signature.

Under the legislation, the manufacture, sale, distribution and advertising of "look-alikes" would be illegal. Violation would be a felony punishable by up to five years in prison and a $20,000 fine. Our bill also prohibits possession of "look-alikes", with the first violation being a petty offense and the second a misdeameanor.

The legislation further gives law enforcement the important weapon of civil forfeiture to seize and confiscate "look-alikes" and the equipment used to manufacture "look-alikes" to prevent continued distribution.

Our legislation is carefully drafted, and has received the endorsement of both the pharmacists' and pharmaceutical industries. We have built in safeguards that make it clear we do not intend to ban placebos used by medical personnel or drugs in the market place that were designed prior to the manufacture of the controlled substance which they may resemble.

Last year, I hosted a conference on the National Association of Attorneys General in Chicago on this topic. After a day-long discussion of the nationwide problem of "look-alike" abuse, the association went on record in support of laws prohibiting "look-alikes." Just a year later, over two dozen States have passed laws banning "look-alikes" and many more are currently considering similar sanctions.

But, the sad fact is that unless you and your colleagues in the Congress take on the "look-alike" industry on the national level, we can only win skirmishes and not the war. "Look-alike" distributors operate on a national scale, using the Federal Postal Service, national delivery companies and a network of salesmen. Despite action by the U.S. Drug Enforcement Administration and the Postal Service to restrict "look-alikes", these are only administrative measures that do not have the force and effect of Federal legislation.

There are still some who question the need to ban "look-alikes" in spite of the startling impact they have on our youth. Well, let's make no mistake about the kind of sickening profiteers we are dealing with.

The people who peddle "look-alikes" are the same type of sleazy people who will try anything to promote the drug culture to children just to make a buck. They are creating an atmosphere of acceptance of the drug culture at a much younger age than ever before. And they are doing so at a great danger to the health and well being of our young people.

I'm convinced that if we pass a Federal law with tough sanctions against anyone who would try to peddle this death to our youth, then we will take the profit out of this business and it will dry up.

Thank you again, Chairman Zefferetti, I will be happy to answer any questions you have.

PREPARED STATEMENT OF WILLIAM POLLIN, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

Mr. Chairman, thank you for the invitation to address the important issue of the use of the "look-alike" drugs in our country, especially among our youth. I welcome the opportunity this hearing provides to publicize NIDA's concern about this emerging drug abuse phenomenon. This concern is based on both developmental and health dangers I will subsequently detail. I will also describe current and proposed future activities that we are undertaking in response to this problem.

We are specifically concerned about two major categories of drugs that have become widely available over the last 2 years: (1) True "look-alikes," and (2) over-the-counter (OTC) stimulants and depressants. True "look-alikes" are products that mimic in size, color, shape, or markings drugs such as amphetamines or quaaludes—prescription stimulants and depressants—or cocaine. "Look-alikes" promoted as "uppers" for their amphetamine-like properties generally contain one on more of the following nonprescription stimulants: Caffeine, phenylpropanolamine (PPA) or ephedrine. "Look-alike" products marketed as tranquilizers or "downers" usually contain only antihistamines.

The OTC drugs that concern us are stimulants and depressants which do not require prescriptions because they are not registered under the Controlled Substances Act. Most of these psychoactive substances are marketed as diet aids, "pep" pills, or sleep aids. They are not manufactured to deceive the public and do not look like controlled substances; however, these products contain many of the same ingredients (PPA, caffeine, ephedrine, etc.) in various combinations, as do the "look-alikes."

We believe that both these categories of products contribute significantly to the national drug abuse problem, particularly by young people. The manufacturers of "look-alike" drugs promote their products through college newspapers, handbills at truckstops, unsolicited literature from mail order firms, or through store front operations often located near high school or college campuses. The distributors promote the drugs as "100 percent legal" or "legal stimulants." In some cases, the products are advertised by the common street names for amphetamines and barbiturates, such as Black Beauties or Yellow Jackets, and because of their physical appearance, the buyer may be led to believe that he or she is purchasing a controlled substance.

OTC psychoactive drugs have apparently shown a recent substantial spurt in number and use. In 1979 an FDA panel of experts concluded that PPA was an effec-

tive appetite suppressant. Since the adoption of their report, there has been a sharp increase in the numbers of diet and energy pills being marketed. Though these are legal stimulant drugs, they are readily abusable. We are concerned about the possible relationship of this newly prominent group of easily available and heavily marketed "legal" psychoactive drugs to older, better known patterns of drug abuse. We believe that significant numbers of individuals may be using these substances for recreational, "legal" highs. These in turn can act as stepping stones to use of other drugs, or contribute to making the drug experience an increasingly important or central part of life.

The advent of "legal" recreational drugs, other than alcohol, is a relatively new phenomena. It is still poorly defined and, and thus the available "hard" data are less firm than for other drugs or drug categories, such as marijuana or PCP. What data we do have, however, strongly suggest a significant increase in recent use. This may well be the most rapidly increasing drug area, in terms of use levels. Such a trend is particularly noteworthy, and disturbing, when most other drug use is on the downturn.

Perhaps the most relevant data come from the NIDA High School Senior Survey. Although these data are somewhat inferential, the survey indicates that of the 16 classes of drug use monitored, only "stimulant-use" showed a statistically significant increase in the last year. Stimulate use is of considerable importance since this is the most widely used class of illicit drugs, after marijuana. One-third of all 1981 high school seniors (32 percent) indicate having at least tried stimulants without medical supervision and one-half of these students (16 percent) say they have used in the past month. All of these statistics show a continuing increase over the past 3 years, but a particularly sharp increase from 1980 to 1981. The authors of the High School Senior Survey indicate they believe "that some of those reporting stimulant (amphetamine) use in the last few years have erroneously included the use of over-the-counter stay-awake and diet pills, as well as other pills intentionally manufactured to look like amphetamines and sold under names which sound like them, but which contain no controlled substances." We at NIDA agree, and suspect that much of the dramatic increase in stimulant abuse is a direct function of the large increase in the sale of over-the-counter stimulants and mail-order pseudoamphetamines.

A comparison of high school senior marijuana and stimulant use over the last 7 years (1975–81) is indicative of the magnitude of the problem we are discussing today. Note that while daily use of marijuana has been declining over the last 3 years, from 10.3 percent to 7 percent, the daily use of stimulants has more than doubled (i.e., 0.5 percent to 1.2 percent). It is precisely in this same time frame that legal stimulants have become widely available. A recent longitudinal study conducted in Canada by the Alcoholism and Drug Addiction Research Foundation also reports similar increases in nonprescription stimulant use.

The Drug Abuse Warning Network (DAWN) emergency room visits and medical examiner reports for amphetamines during the period 1978 to 1980 have also shown substantial increases. During this time, amphetamine mentions have increased by approximately 80 percent, while medical examiner mentions have increased by 40 percent. (One possible contributing factor to this difference in the rate of increase is that medical examiner reports are verified by toxicological examination, while emergency room reports are not. It is likely that here, as in the High School Senior Survey, the self-reported use of amphetamines may include "look-alikes" and diet aids, which would imply that the use of these products results in more health-related emergencies that is currently recognized.) DAWN OTC diet aid mentions have also been increasing steadily since 1979, with especially sharp increases in 1980, and continues to rise to date.

HEALTH EFFECTS

A principal concern regarding health effects of "look-alikes" and other OTC stimulants and depressants is the developmental danger they pose for young Americans. For maturing adolescents, the major danger in drug abuse is developing a pattern of use of drugs as a shortcut to pleasure, and subjective highs as a substitute for satisfaction derived from realistic achievement. There is the danger that this shortcut to pleasure, before they have learned the necessary skills and attitudes to be productive adults, will come to dominate and shape their subsequent development and lives. Easy availability of legal highs increases the likelihood of this developmental pattern's emergence.

This imitation drug scheme has had serious harmful physical and psychological effects, particularly on teenagers and children.

"School children and others who don't normally abuse drugs are introduced to "look-alikes and told they're legal and safe.

"Imitation drugs give the impression that real controlled substances are not as potent and dangerous as they really are.

"Traditional drug abuse education programs are thwarted by the wide availability of the imitation drugs.

"Look-alikes have created a market for stimulant use.

"Physicians and poison centers are deceived by the fake drugs.

"Law enforcement officials are confounded in their efforts to stop illegal traffic of real controlled substances."

In terms of physical effects, there have been several well documented reports of cerebral hemorrhages with death and severe hypertension associated with the use of "look-alike" drugs. Caffeine is a stimulant of the methylxanthine class. This class is represented by theophylline, caffeine, and theobromine. Untoward reactions to caffeine are mainly referrable to the central nervous and circulatory systems. Symptoms include insomnia, restlessness, excitement, as well as tachycardia and extrasystoles. Ephedrine and phenylpropanolamine are adrenergic stimulants. The administration of ephedrine may cause anxiety, restlessness, weakness, throbbing headache, respiratory difficulty, and palpitation. More serious side effects consist of cerebral hemorrhage and cardiac arrhythmias. The toxic effects of phenylpropanolamine (PPA) are similar to those of ephedrine. These substances have marked cardiovascular effects. However, the central nervous system effects of PPA and ephedrine are considerably less marked than amphetamine, and substantial quantities are required to produce the desired euphoric effects. At these high dose levels the cardiovascular system is under considerable stress and in susceptible individuals may fail.

NIDA'S EFFORTS AND ACTIONS

1. Task force

Early this year, the Institute convened a task force on the "look-alike" drug problem. The purpose of this working group has been to coordinate with other Federal agencies (e.g., FDA and DEA) and develop strategies for action against these substances. The activities that are described below are new or proposed initiatives to address this problem.

2. Improve data collection procedures

Although an assessment of the full nature and extent of the abuse of these substances is presently unknown, the Institute has determined that one of our main priorities will be to initiate improved data collection procedures concerning these substances. In the future, these will provide a more precise picture of the extent and trends of their use in the High School Senior Survey and DAWN. The 1982 High School Senior Survey, for the first time, specifically distinguishes between amphetamines and "look-alikes." NIDA has sent out an alert on the nature and extent of problems and health consequences of "look-alikes" to the reporting units (emergency rooms and medical examiners) of DAWN.

3. Alert the professional community and general public

Another major initiative is to alert the professional community and the general public about the "look-alike" problem. A NIDA Capsule—fact sheet—on the "look-alike" drugs is being sent to hospitals, drug abuse treatment programs, Single State Agencies, community mental health centers, and a number of other public and private sector agencies. We are also preparing a "Clinical Notes" issue which will be used to alert the health professional community to the dangers of the use of the "look-alike" drugs.

4. State and local legislation

Through our ongoing activities with the National Parents Movement, we have provided information and technical assistance to help them support and facilitate the passage of State and local legislation to control the use of "look-alike" drugs. We have included the abuse of "look-alike" drugs as an issue in two Regional Family Workshops which have involved representatives of parents groups, Single State Agencies for Drug Abuse Prevention, and other public health officials. We have also discussed issues related to the "look-alike" abuse phenomenon at a meeting of the National Association of State Alcohol and Drug Abuse Directors. This organization serves as one of our links with the Single State Agencies and also facilitates our dissemination of early warning information to State and local treatment and prevention groups.

We are currently reviewing with the American Medical Association (AMA) how best to alert the medical community, and we are specifically exploring the potential of putting information about the "look-alike" problem in the developing AMA drug information data bank. Contact with additional and varied professional organizations is also under way.

A major aspect of NIDA's effort in seeking to prevent and treat drug abuse problems and other health-related conditions has been the exploration of commonalities in the volitional behaviors, e.g., drug abuse, alcoholism, obesity, cigarette smoking, gambling, etc., and the development of approaches which can prevent or influence the course of development of these compulsive behaviors. Emphasis on a health promotion model, in which activities are encouraged which enhance wellness and prevent disease, is not only consistent with NIDA's general mission to foster development of more effective drug abuse prevention programs, but should also have an effect in the specific area of use of "look-alike."

Mr. Chairman, in summary, NIDA believes that the issue of legal recreational drugs is a serious national problem and deserving of the attention this hearing constitutes. Many researchers are convinced that there are developmental sequences in drug use; that legal drugs can be an integral and significant part of this sequence; and that their use may precede and predispose to the use of illicit drugs. These substances appear to show a substantial current increase in use, when most drugs are showing a decrease among teenagers. For these reasons, NIDA will place increasing emphasis on better data collection and prevention efforts targeted at "look-alike."

Thank you. I will be glad to answer any questions you may have.

HIGH SCHOOL SENIOR DRUG USE

1975 - 1981

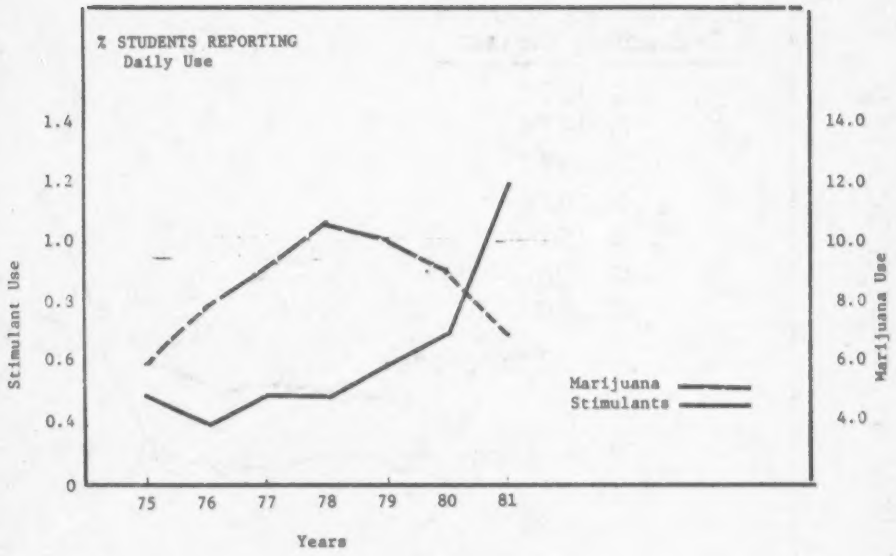
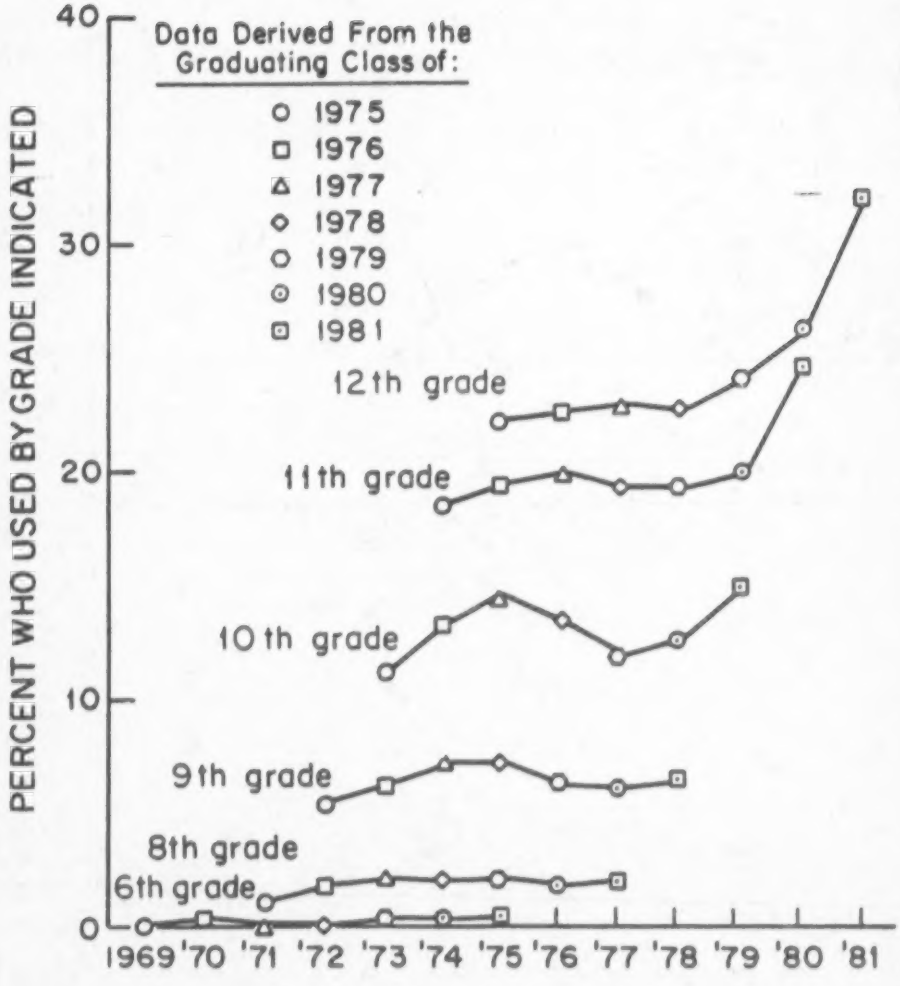


FIG. 1

Stimulants: Trends in Lifetime Prevalence for Earlier Grade Levels
Based on Retrospective Reports from Seniors



NIDA Capsules

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HIGH SCHOOL SENIOR DRUG USE: 1975-1981

The following table shows the percentage of high school seniors from the classes of 1975 through 1981 who have used drugs of abuse. These numbers were gathered in annual nationwide surveys conducted by the University of Michigan Institute for Social Research for the National Institute on Drug Abuse. The seven surveys have involved more than 100,000 high school seniors from public and private schools.

	Ever Used							Daily Users							Used in Past Month							Used in Last Year						
	Class of							Class of							Class of							Class of						
	'75	'76	'77	'78	'79	'80	'81	'75	'76	'77	'78	'79	'80	'81	'75	'76	'77	'78	'79	'80	'81	'75	'76	'77	'78	'79	'80	'81
Marijuana	47%	53%	50%	50%	60%	60%	66%	6%	8%	9%	10.7%	10.5%	9.1%	7%	27%	32%	35%	37%	37%	34%	33%	49%	45%	48%	50%	51%	49%	46%
Inhalants	NA	10	11	12	13	12	13	NA	0.6	0.6	0.1	0.6	0.1	0.1	NA	1	1	2	2	1	2	NA	2	4	4	5	5	
Amyl & Butyl Nitrites	NA	NA	NA	NA	11	11	10	NA	NA	NA	NA	0.6	0.1	0.1	NA	NA	NA	NA	2	2	1	NA	NA	NA	NA	7	6	
Hallucinogens	15	15	14	14	14	13	13	0.1	0.1	0.1	0.1	0.1	0.1	0.1	5	5	4	4	4	4	4	11	9	9	10	10	9	
LSD	11	11	10	10	10	9	10	0.0	0.0	0.0	0.0	0.0	0.0	0.1	3	3	2	2	2	2	3	7	6	6	6	7	7	
PCP	NA	NA	NA	NA	13	10	8	NA	NA	NA	NA	0.1	0.1	0.1	NA	NA	NA	NA	2	1	1	NA	NA	NA	NA	7	4	
Cocaine	9	10	11	12	15	16	17	0.1	0.1	0.1	0.1	0.2	0.2-	0.3	2	3	3	4	6	5	6	6	6	7	9	12	12	12
Heroin	2	2	2	2	1	1	1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Other Opiates	9	10	10	10	10	10	10	0.1	0.1*	0.2	0.1	0.0	0.1	0.1	2	2	3	2	2	2	3	5	5	6	6	6	6	6
Stimulants	22	23	23	23	24	25	22	0.5	0.4	0.5	0.5	0.6	0.7	1.2	9	8	8	9	10	12	10	15	15	16	17	18	21	20
Sedatives	18	18	17	16	15	15	14	0.3	0.2	0.2	0.2	0.1	0.2	0.2	5	5	5	4	4	5	5	12	11	11	10	10	10	9
Barbiturates	17	16	16	14	12	11	11	0.1	0.1	0.2	0.1	0.0	0.1	0.1	5	4	4	3	3	3	3	11	10	9	8	8	7	7
Methaqualone	8	9	9	8	8	10	11	0.0	0.0	0.0	0.0	0.0	0.1	0.1	3	3	2	2	2	3	3	5	5	5	5	6	7	8
Tranquilizers	17	17	16	17	16	15	15	0.1	0.2	0.3	0.1	0.1	0.1	0.1	4	4	5	3	4	3	3	11	10	11	10	10	9	8
Alcohol	88	92	93	93	93	93	93	5.7	5.6	6.1	5.7	5.9	5.6	5.6	65	68	71	72	72	72	71	85	85	87	88	88	88	87
Cigarettes	74	75	76	75	74	71	71	28.9	28.8	28.8	27.5	28.4	21.3	20.3	37	39	38	37	34	31	29	NA	NA	NA	NA	NA	NA	NA

NA indicates data not available
* indicates less than 1.0%

Terms:
Ever Used: Used one or more times.
Daily Users: Used 20 or more times in the month before survey.
Used in Past Month: Used at least once in the 30 days prior to survey.
Used in Last Year: Used in the 12 months prior to survey.

Source: *Student Drug Use in America: 1975-1981*, National Institute on Drug Abuse.

Note: Separate questions about the use of PCP (angel dust) and amyl and butyl nitrites (poppers) were not asked until 1979.

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The one other class of drugs showing a sharp decline at present is the amyl and butyl nitrites, inhalants which are known on the street by names like "poppers" and "snappers." The number of seniors using these drugs during the prior year dropped from 6.5 percent in 1979 to 3.7 percent in 1981.

In the case of tranquilizers, a much more gradual decline, which began in 1978, continued into 1981. Across the last 4 years, the annual usage statistic for nonmedically supervised tranquilizer use has fallen from 11 to 8 percent.

Not all drugs showed a decline in use. Heroin, barbiturates, and LSD remained quite steady this year, although this follows and earlier period of decline for each of these drugs. (In the case of LSD, the degree and duration of the highs experienced by recent users did continue their earlier decline).

The use of opiates other than heroin remained steady this year, as it has since 1975, though the degree and duration of the highs experienced by users have both dropped over the period.

Another drug which has remained fairly steady for the last 2 years, after a sharp rise in popularity, is cocaine. Between 1976 and 1979 the proportion of seniors using cocaine during the prior year doubled, from 6 to 12 percent. Since then, however, that statistic has increased by only four-tenths of one percentage point for the Nation as a whole. However, there are large regional differences in the use of this drug. Cocaine use continues to rise in the West and Northeast, and fall in the South and North Central.

Only amphetamines showed a statistically significant increase this year. Amphetamine use is of considerable importance since this is the most widely used class of illicit drugs other than marijuana. One-third of all 1981 seniors (32 percent) indicate having at least tried amphetamines without medical supervision, and one-sixth (16 percent) say they have used in the past month. All of these statistics show a continuing increase over the past 3 years, but a particularly sharp increase from 1980 to 1981. (For example, lifetime prevalence rose by one-fourth this year, annual prevalence by one-fourth, and monthly prevalence by almost one-third.

These sharp upward trends may be exaggerations of the true amphetamine use trends, however. In the past 2 years there has been a large increase in the sales of over-the-counter stimulants and of mail-order pseudo-amphetamines. Thus, an increased number of users of these noncontrolled substances may mistakenly report them under amphetamine use.

The statistics (except monthly use) on use of the sedative-hypnotic methaqualone also continued an earlier rise this year, although it was more gradual than before. Lifetime prevalence now stands at 11 percent for seniors, up from 8 percent in 1978.

All measures of alcohol use remained virtually unchanged, including daily use which has consistently stayed at about 6 percent since 1975. Occasional binge drinking, that is, taking five or more drinks in a row at least once during the prior 2-week interval, has also remained steady since 1979 at 41 percent of all seniors.

In summary, the use of many illicit drugs has declined, or is declining, significantly from the peak levels of the 1970s. Further, the current users of most of these drugs appear to be taking them in somewhat smaller doses or quantities than was true of earlier users, since there has been some drop in the reported degree and duration of the "highs" usually experienced with them. (This is true in the case of marijuana, amphetamines, LSD, cocaine, methaqualone, barbiturates, and opiates other than heroin. It is not true for alcohol, tranquilizers, or hallucinogens other than LSD.)

Despite these tangible improvements, illicit drug use is still extremely prevalent among American young people of high school age. In the graduating class of 1981, two-thirds (66 percent) admitted to at least some illicit use of a drug, a conservatively low estimate. While a third of users (23 percent of the total sample) have used only marijuana, two-thirds of users (43 percent) have used some other illicit drug(s), usually in addition to marijuana. We judge these still to be very high levels both in absolute terms, and relative to other countries. In fact, they are still probably the highest levels of illicit drug use among young people to be found in any industrialized Nation in the world. Thus, while some improvements are definitely beginning to emerge, the problems of drug use and abuse are still a very long way from being solved.

PREPARED STATEMENT OF SORELL L. SCHWARTZ, PH. D.

Mr. Chairman, my name is Sorell L. Schwartz. I am Professor of Pharmacology at Georgetown University School of Medicine, and hold a Ph.D. in pharmacology from the Medical College of Virginia, Virginia Commonwealth University. Since receiving

the degree in 1963, my area of concentration has primarily been in toxicology. A copy of a curriculum vitae detailing my educational, research and other professional background has been provided.

The opportunity to appear before this Committee to discuss the problem of "look-alike" drugs is welcome. Look-alike drugs, as you know, are counterfeits of certain prescription drugs that are identified in the effects on the central nervous system that cause drug seeking behavior and drug abuse in a portion of the population. The alleged "benefits" of look-alikes is that they contain over-the-counter drugs (OTC) approved for sale without a prescription—the idea being that they can be used without fear of breaking the law. There appears to be a belief that because of the OTC classification of look-aiikes, they are also safe. This is a belief which, if not endorsed by the FDA, has not been denied with any particular degree of energy. On the basis of current scientific and clinical knowledge, it is inappropriate to consider the major sin of look-alikes to be that they are counterfeits. What is appropriate is to consider look-alike as drug preparations with no benefit other than pandering to drug seeking behavior but associated with risks of damage to health including fatal reactions.

Generally, look-alikes contain phenylpropanolamine (PPA) and/or ephedrine and/or caffeine. In order to understand the evaluation of the view that look-alikes are benign with respect to health effects, it is useful to review the pattern of PPA usage as a drug.

PPA is a drug which is chemically related to amphetamine and other "speed like" drugs. Amphetamine is known for its ability to stimulate the central nervous system to cause a euphoria—thus its attraction as a drug of abuse; for its anorectic activity—i.e. appetite suppression effect; and for its ability to increase blood pressure. The means by which amphetamine exerts its effect on blood pressure is to constrict blood vessels (vasoconstriction).

Early studies with PPA suggested that it had little of the effects of amphetamine and that its major activity is to constrict small blood vessels. Since the small blood vessels in the nasal tissues are dilated during nasal congestion, PPA—because it could constrict these small blood vessels—found use as a nasal decongestant when taken orally. However, because of its chemical similarity to amphetamine and because some people who used PPA as a decongestant reported decreased appetites, it was ultimately marketed as an OTC anorectic drug—an aid to complying with a reduced calorie diet.

A panel convened as part of the FDA OTC drug review concluded that PPA was effective and safe when used as an anorectic OTC agent. Notwithstanding that the overwhelming majority of medical opinion considers the use of anorectic drugs as an inadequate approach to promoting permanent weight loss in obese individuals, there was and still is little data to support the conclusion that PPA is an effective anorectic drug. More to the point of this discussion, there is accumulating data to suggest that PPA is not as safe as the panel imagined. (Part of the problem is that the panel was made up of a group of people highly qualified in their particular areas of concentration. Unfortunately none of the areas appeared to be concerned with clinical pharmacology and with toxicology.)

It now appears that PPA has a much greater likelihood of affecting blood pressure than originally believed. As early as 1965 and 1966 there were reports of incidents of transient hypertension following PPA ingestion.[1] [2] Often, advese reactions to drugs are first noted in a particular region primarily because first one physician makes an observation, this is then communicated to colleagues who are then "sensitized" and more observations are made. In the case of PPA, the problem of hypertension had its first major focus in Australia. These reports were in 1978,[3] 1979,[4] [5] [6] and 1980.[7] In the latter report the investigators studied the effect of a single capsule

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[1] Ostern, S. and W. H. Dodson. Hypertension following Ornade ingestion. J. Amer. Med. Assoc. 194: 472 (1965).

[2] Livingston, P.H. Transient hypertension and phenylpropanolamine. J. Amer. Med. Assoc. 196: 1159 (1966).

[3] Frewin, D. B., P. O. Leonello and M. E. Irewin. Hypertension after ingestion of Trimolets. Med. J. Aust. 2: 497 (1978).

[4] Horowitz, J. D., J. J. McNeil, B. Sweet, F. A. O. Mendelsohn and W. J. Louis. Hypertension and postural hypertension induced by phenylpropanolamine (Trimolets). Med. J. Aust. 1: 175 (1979).

[5] King, J. Hypertension and cerebral hemorrhage after Trimolets ingestion. Med. J. Aust. 2: 258 (1979).

[6] Lee, K. Y., L. J. Beilin and R. Vandongen. Severe hypertension after ingestion of an appetite suppressant (phenylpropanolamine with indomethacin). Lancet 1: 1110 (1979).

[7] Horowitz, J. D., L. G. Howes, N. Christophidis, W. J. Lang, M. R. Fennessy, M. J. Rand and W. J. Louis, Hypertensive responses induced by phenylpropanolamine in anorectic and decongestant preparations. Lancet 1: 60 (1980).

(50 mg in one preparation and 85 mg in another) in medical students. With the high dose (85 mg) preparation, 12 of 37 subjects experienced increases in blood pressure which were diagnostically classified as hypertensive responses.

Hypertensive responses to PPA have now been documented on numerous occasions in this country and other countries, and suggestions have been made that since PPA has little proven therapeutic benefit, it should be withdrawn from the market in light of the possible side effects.[8] [9]

PPA has very weak properties with respect to stimulation of the central nervous system. Therefore, it is likely that a look-alike "user"—expecting an amphetamine-like euphoria—will increase the dosage of the PPA-containing look-alike. In fact, it may very well be that PPA is more like amphetamine in blood pressure effects than it is in stimulating the central nervous system. Thus the possibility for eliciting a hypertensive response in pursuit of a euphoric response is a strong one. Now, consider the presence of ephedrine. It, too, is an OTC drug which can increase blood pressure. In doing so, it ultimately causes a response which will be additive and perhaps synergistic with that of PPA.

On purely predictive grounds, some incidence of hypertensive crisis should be expected in the look-alike user population. These expectations have been met. There are three well documented cases of look-alike deaths associated from intracranial hemorrhage in New Mexico. This documentation is based on work done by the Center for Forensic and Environmental Science at the University of New Mexico School of Medicine. Further studies by this unit revealed at least 20 look-alike associated admissions to emergency rooms in Albuquerque over a six month period. Other cases have also come to light and as emergency room physicians become aware of the necessity to include look-alikes in their history taking and diagnostic criteria, it is reasonable to assume that many more deaths will be attributed to look-alikes and perhaps thousands more emergency room admissions.

The similarity of the toxic effect of PPA and ephedrine to the toxic effects of amphetamine are not limited to effects on the blood pressure. Mental disturbances known to be associated with amphetamine abuse have also been observed individually for PPA and ephedrine. These effects include restlessness, instability, aggressiveness, sleep disturbance, hallucinations and psychotic episodes.[9] [10] [11] Here again whether PPA and ephedrine in combination would be additive or synergistic is speculative but the fact that the combination is potentially inimical to health is not.

I became involved in the problem of look-alikes as a result of my working with the U.S. Postal Service. In particular, my work has been with the Special Investigations Division and the Consumer Protection Division on mail fraud concerning medical areas. With regard to the subject at hand, I have advised the Postal Service that claims of efficacy and safety for PPA-containing diet aids distributed through the mail are not substantiated by current scientific and clinical data and that look-alikes containing PPA and ephedrine alone, in combination with each other or in combination with caffeine represent a hazard to health. Even without the clinical data to support this conclusion, the fact that PPA and ephedrine in combination with each other or with caffeine has not been adequately studied for toxicity, is grounds enough for questioning safety.

I suggested to the Postal Service that it is likely that help could be received from the FDA, which has much broader powers for matters such as these. It has been my impression that what cooperation the Postal Service might have received from the FDA has been unenthusiastic, at best. Part of the problem may be the FDA cannot question safety of PPA or PPA and caffeine-containing look-alikes without questioning the safety of similar preparations sold in neighborhood pharmacies as diet aids.

The investigative efforts of the FDA regarding look-alikes, which I have observed, are not very impressive. For example, two of the deaths attributed to look-alikes in New Mexico received public notice and were investigated by the FDA. When a young person suffers from a cerebral hemorrhage, it is generally attributable to an aneurysm resulting from congenital defects. This is reflected in the FDA investigation.

For Subject A, the FDA investigator's report concludes: "On 2/13/81 I talked with [name of lay investigator] with the Office of Medical Examiners. He stated that the cause of death was cerebral hemorrhage due to an anurism (sic). The anurism (sic)

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[8] Bennett, W. Hazards of the appetite suppressant phenylpropanolamine. Lancet 2: 42 (1979).
[9] Roxanas, M. G. and J. Spalding. Ephedrine abuse psychosis. Med. J. Aust. 2: 639 (1977).
[10] Norvenius, G., E. Widerlov and G. Lounerholm. Phenylpropanolamine and mental disturbances. Lancet 2: 1367 (1979).
[11] Dietz, A. J. Amphetamine-like reactions to phenylpropanolamine. J. Amer. Med. Assoc. 245: 602 (1981).

could have burst for a number of reasons, physical exertion, sexual activity, etc. anything which would raise the blood pressure. He also stated that the legal stimulants would have also increased the blood pressure but that he did not know if he could show a direct association. When the OME finishes their report, a copy will be sent to me and forwarded on for attachment."

For Subject B, her report concluded: "On 2/13/81 I talked with [name of the same lay investigator] with the Office of Medical Examiners. He stated that the cause of [subject's first name] death was cerebral hemorrhage due to an anurism (sic). He stated that he did not think that a direct association could be made between the death and the legal stimulants as numerous things could have caused the anurism (sic) to rupture. He stated that the anurism (sic) would have ruptured [as] a result of increased blood pressure and that although the legal stimulants would increase the blood pressure so could a number of things such as physical exertion, sexual activity etc. When the OME finishes their report, a copy will be sent to me and forwarded on for attachment to this report.

"No further investigation was performed."

The lay investigator she referred to is not a pathologist nor a physician, or scientist for that matter even though he provided her with an identical medical conclusion for both cases.

The New Mexico officials specifically looked for evidence of an aneurysm and found none for either Subject A or B or for a third subject they studied. The autopsy reports for Subjects A and B reflect this. These two subjects and the third suffered the cerebral hemorrhage proximate to having ingested look-alikes. It is the current opinion of the pathologist who has studied the cases that a causal relationship between the look-alikes and the deaths is a strong possibility.

This is not to say that the evidence is unequivocal that look-alikes caused these deaths. However, the investigation by the FDA does not accurately reflect the facts or the level of concern.

I might add that what protection the population has received from the distribution of look-alikes has been from the Postal Service by a very dedicated group of postal inspectors within the Special Investigations Division and an equally persistent group of attorneys within the Consumer Protection Division. The laws that the Postal Service has to work with were not really designed to handle the breadth of the problems associated with look-alikes but the Service has been effective in keeping distirbutors from operating with impunity and in bringing the issue before the public.

I trust that this information will be useful to the Committee in its consideration of the problem of look-alike drugs.

PREPARED STATEMENT BY WARNER-LAMBERT CO.

Mr. Chairman and members of the committee, Warner-Lambert is pleased to have the opportunity to provide this written statement, and to appear, before the Committee, on behalf of its Capsugel Division, which supplies empty gelatin capsules to the pharmaceutical industry.

My name is Charles E. Lents, Counsel, Regulatory Affairs, Warner-Lambert Company. For the past year I have been reviewing the "controlled drug—look-alike" problem in an effort to ascertain what steps Capsugel can take to minimize this serious public health problem.

I am accompanied today by Mr. Ronald E. Zier, Vice President Corporate Public Affairs, Warner-Lambert Company. Mr. Zier has been working with concerned trade associations, public relations personnel, and professional groups in an effort to develop public awareness programs concerning drug abuse which can be targeted at the younger age groups. Also with me today is Mr. William Goodridge, Director Corporate Security, Warner-Lambert Company. Mr. Goodridge has been involved in the development and implementation of certain efforts which Capsugel has taken to discourage the production and distribution of "controlled drug look-alikes" I will discuss these efforts later in this presentation.

As we indicated in our previous October 26, 1981 statement to the Select Committee, Warner-Lambert's Capsugel Division and its predecessors have achieved considerable expertise in the production of gelatin capsules for medical and therapeutic purposes. We have been making capsules for nearly 100 years, having begun in 1888. Capsules are manufactured and marketed on a worldwide basis to other pharmaceutical companies which fill them with their own chemical ingredients and then market them as their own products with their own trade name and individual markings. Capsules are produced at our Greenwood, South Carolina manufacturing

facility as well as at other manufacturing locations in Europe, Asia and Latin America.

As we previously indicated we have been focusing on the "controlled drug look-alike" problem since the spring of 1980. The problem was brought to our attention as a result of trade press articles and feedback from our sales representatives and professional staff.

To many, the "controlled look-alike drug" problem may appear to be a phenomena of the present day, but its roots, as far as society and industry are concerned, are deep and closely parallel the drug problem of the late 60's and early 70's. The traumatic effect of the "look-alike" problem has been more pronounced within the last year because we have witnessed the youth of our nation falling victim to the insidious enticement of individuals purporting to help alleviate the drug problem by diverting drug abusers to legitimate OTC drugs. In reality their motives are strictly profit oriented. The current problem appears to draw no distinction between economic or social groups.

Last year we informed you that Capsugel had initiated certain actions which we felt would discourage improper use of its capsule products. Our actions included the stopping of imprinting of copy on capsules of certain colors, and the actual stopping of the manufacturing of specific capsule color combinations and sizes which we determined to be popular in the illicit drug trade. Thus, in 1981, we stopped taking orders for size numbers 1 and 3, black/black and yellow/yellow capsules which were commonly associated with amphetamine, or "speed" type products. We then sent a letter to our capsule customers asking for verification that customers products, produced with Capsugel manufactured capsules, we being distributed in accordance with applicable local, state and federal laws. We also required that complete labeling, including package inserts, if applicable, be submitted to Capsugel.

The letter said that after reviewing such material, a determination would be made whether the finished product was a legitimate generic, for which capsules would continue to be supplied, or a "look-alike" substitute for a controlled substance. Orders for these capsules, consistent with the previously adopted policy, would not be accepted. To date very few purchasers have attempted to justify the receipt of black/black and yellow/yellow capsules.

One customer's order, however, has been accepted after a careful review of the products labeling showed it not to be a "controlled drug look-alike."

The above was a voluntary good faith effort on Capsugel's part. At that juncture, we believed that we had taken appropriate action to curtail the supply of capsules in the size and color combinations reportedly favored as "controlled drug look-alikes." In recent months, however, there has developed a trend to utilize capsules with non-imitating color combinations and/or markings, which, we are told by federal officials, are then popularized through word-of-mouth advertising and marketing practices as containing controlled drug(s) as the active ingredient(s). The public, in general, and our youth, in particular, are being victimized by these misleading practices which often result in physical injury or even death to the users. All responsible individuals will agree that misrepresenting any drug, however legitimate, as a controlled drug is medically damaging and not in the best interest of legitimate pharmaceutical manufacturers, distributors or the consuming public.

In late 1981 and early 1982 Warner-Lambert Company and its Capsugel Division initiated a program to ascertain what additional steps could be taken to curtail this reprehensible practice. We contacted each of the involved federal regulatory and law enforcement agencies as well as the staff of this Committee for advice and counsel. We received an excellent reception, encouragement and assistance from all parties. At that time we also involved our field sales force and instructed them to alert us whenever they received a suspicious order. We received reports from the field such as:

"While we would not sell them any look-alike capsules, the new thing is apparently "non look-alike look-alikes" (i.e., any color combination) and we have no way to screen such orders." and

"We asked for and received label copy which, on the surface, represents a legitimate product.—Do we honor the order on the basis that if this is marketed as a "look-alike,"—X Company—defrauded us? Or, do we refuse the order; and, if so, on what basis."

These two statements characterized three major dilemmas we faced as a capsule manufacturer. The first relates to the hundreds of colors and color combinations which can be used to produce "look-alikes" and "non look-alike look-alikes." The second concerns our desire not to be a deterrent to the marketing of legitimate generic products. The third relates to allegations of improper restraint of trade. With

regard to this latter point, we have received indications from some capsule customers that we may be the target of civil antitrust litigation for refusing to sell to them.

As we previously indicated Warner-Lambert's Capsugel Division operates on a global basis. At a meeting earlier this year in Basel, Switzerland, attended by many of our key worldwide capsule personnel, we addressed the current U.S. problem and issued instructions to be on the look-out for similar trends developing in international countries. We advised them to be especially alert to attempts to improperly divert internationally produced capsules into the United States. A specific action program was developed and communicated within the Capsugel Division on a worldwide basis.

The international Capsugel program already has paid dividends. In late July 1982 we were informed that a party in the United Kingdom wanted to place an order for twenty million #3 black-black capsules, ten million #1 black-black capsules, ten million #1 yellow-yellow-capsules and ten million #3 yellow-yellow capsules. Delivery was to be within twelve months starting in August 1982. As you know, black-black and yellow-yellow are the most popular "controlled drug look-alike" color combinations. It was ascertained that the order was being placed by a third party company who were trying to obtain capsules on behalf of a United States company who were unable to obtain the capsules from Capsugel in the United States. It is, thus, evident that "controlled drug look-alike" manufacturers, not being able to obtain capsules in the United States, may turn to international areas to obtain their supplies even though the cost would undoubtedly be higher. Needless to say, our international organization would not honor this request. We are concerned, however, that we may not always be able to detect such orders and potential domestic or international diversions may occur due to the very large number of possible capsule color combinations.

In recent months Capsugel has decided to initiate a number of new actions which we hope will further discourage the manufacturers and distributors of these products. These steps which will be instituted in the United States, include, or will shortly include, the following:

1. We will require all Capsugel customers to sign the attached draft "Statement and Continuing Guarantee" form. We will provide the completed form to appropriate federal, state and local law enforcement agencies and government bodies upon request.

2. We will refuse to sell additional look-alike capsule color combinations when orders are determined to violate the "Statement and Continuing Guarantee" form.

3. We will expand our policy regarding imprints which we feel to be the same or confusingly similar to look-alike trade markings.

4. We will program our computers with customer names, capsule color combinations purchased and copy imprinted on such capsules.

5. Computer print-outs of the above information will be provided to appropriate law enforcement agencies and governmental bodies when such agencies are involved in an official investigation.

Your letter inviting us to appear here today asked that we discuss the above "Statement and Continuing Guarantee" proposal. Its rationale is based upon our desire to make it clear to prospective customers that Capsugel will not supply capsules except under the conditions spelled out in the Guarantee. We believe use of the "Statement and Continuing Guarantee" will deter unscrupulous manufacturers from using capsules to make controlled drug look-alikes or products that do not specifically imitate the appearance of controlled drugs but may be advertised and sold as containing controlled substances. Also, the form will provide law enforcement authorities with an investigative tool which may be helpful in identifying persons or firms who may be violating the law. The staff of the Select Committee has been of great assistance to us in developing the proposal. Through them a recent draft has been made available to various members of the regulatory and law enforcement community. We have received comments, suggestions and sufficient encouragement such that Warner-Lambert intends to fully implement the program in the near future.

As you will note, we will require all Capsugel customers to sign, and certify to Capsugel that "No capsules heretofor or hereafter obtained from the Supplier are or will be knowingly used by Purchaser or, to Purchaser's knowledge, by its distributees, in the production, encapsulation, packaging or marketing of any product which is in violation of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Controlled Substance Act (21 U.S.C. 801 et seq.) or any corresponding law of any state or local authority."

Also the purchaser must specifically warrant that "no capsules heretofore or hereafter obtained from Supplier is or will be knowingly used by Purchaser or, to

Purchaser's knowledge, by its customers or distributees, in the production, encapsulation, packaging or marketing of any illegitimate product, or any legitimate product, which is likely to confuse, mislead or be falsely misrepresented to any person as being the same as or similar in content to a Controlled Substance." The Statement and Guarantee "shall be continuing and shall remain in force until revoked in writing by Purchaser."

Lastly, the Continuing Guarantee provides that "Purchaser hereby authorizes Supplier to provide a copy of this document to governmental departments or agencies having jurisdiction to determine whether or not said capsules, and the products of which they are a part, are being utilized in conformity with applicable federal, state and local laws. Purchaser acknowledges that the providing of this document to such a governmental body by Supplier shall be considered to be a submission of Purchaser directly to that governmental body; and that such governmental body may rely upon the contents hereof."

We have discussed the "Statement and Continuing Guarantee" with outside legal counsel and are of the opinion that a knowing violation of its terms would be actionable under a number of federal statutes, which, directly or indirectly, bear upon the activities involved in the distribution of controlled drug substances and their "look-alike" counterparts. Liability under existing federal statutes (Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.; Controlled Substances Act, 21 U.S.C. § 801 et seq.; Crimes and Criminal Procedure, 18 U.S.C. §§ 2 (principals), 1962 (racketeer influenced and corrupt organizations), and 1341, 1343 (mail fraud)), would be based upon the actual activity engaged in rather than upon the signing of the Statememt and Continuing Guarantee and its submission to governmental agencies. However, we believe that if the Statement and Continuing Guarantee were signed with false intent and transmitted to Capsugel through the mail, as most capsule orders are, that this would constitute a violation of 18 U.S.C. § 1341.

Although a statement as to a future condition may be false when made, it is considerably easier to establish the falsity of a statement pertaining to current facts since this does not involve inquiry into the intent of the declarant. For this reason, we have included in the Continuing Guarantee a representation that no capsules heretofore or hereafter obtained from Supplier are or will be knowingly used for proscribed purposes. Further, we have included language expressly acknowledging the continuing nature of the representation. The utility of the Continuing Guarantee will be enhanced by periodical re-execution.

This will both serve as a reminder and to maintain the current quality of the form.

As regards the other Federal statutes mentioned above, we believe it is possible that manufacturers and distributors of "look-alike" drugs could be successfully prosecuted under those enactments assuming appropriate circumstances and adequate proof. The only exception might be the Controlled Substances Act, 21 U.S.C. § 801 et seq. which contains no obvious proscription against "controlled drug look-alikes." However, even here a recent Court of Appeals decision, *United States* v. *Gesualdi*, 660 F.2d 59 (2nd Cir. 1981) appears to have held that the Drug Enforcement Agency is not without authority over non-controlled substances.

Relevant sections of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. would include: Section 331 which makes it unlawful to misbrand a drug, introduce a misbranded drug into interstate commerce or receive or deliver a misbranded drug; and Section 352(i) which provides that a drug is misbranded, "(1) if it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if its is an imitation of another drug; or (3) if it is offered for sale under the name of another drug." As previously indicated, the particular factual situation will be controlling.

We also believe the above "Statement and Continuing Guarantee" has a logical tie-in with recent "look-alike" legislation passed by a number of states. We have specifically reviewed the statutes of the State of New Jersey, where Warner-Lambert has its headquarters. New Jersey, as you may know, has recently adopted an amendment to the New Jersey Controlled Dangerous Substances Act, N.J.S.A. 24:21-1 et seq., prohibiting possession, manufacture and trafficking in "look-alike" drugs. Other state statutes, such as that of Illinois and Pennsylvania, offer enforcement opportunities for local authorities.

In addition, the execution of the proposed "Statement and Continuing Guarantee" could subject the declarant to criminal liability under at least one other New Jersey statute. This is N.J.S.A. 2C:21-7(h) (Deceptive Business Practices) which provides:

"A person commits an offense if in the course of business he:

* * * * * * *

"h. Makes a false or misleading written statement for the purpose of obtaining property or credit."

Under this Section, a purchasing company could be guilty of a crime of the fourth degree if it signed the "Statement and Continuing Guarantee" and the representations contained therein were untrue since the false written statement would have been made in the course of business for the purpose of obtaining property, i.e., empty capsules. There is no requirement that a government agency be involved to make out the offense. We believe other states have similar provisions in their criminal code.

While Warner-Lambert and its Capsugel Division are of the opinion that the above proposals will help to alleviate the "controlled drug look-alike" problem which involves capsules, it will, of course, do nothing to prevent the further developing problem which involves tablets and powders. In fact, existing evidence supports the conclusion that "non-look alike, look-alikes" in the form of pill, tablet and powder products are now appearing using different ingredients other than caffeine, phenylpropanolamine and ephedrine sulfate. Thus, a multi-faceted approach is needed which will involve all the agencies and parties appearing before the Select Committee today. It appears that some overriding Federal legislation is needed that will address the problem in a generic manner. For example, the problem of clandestine laboratories are a federal and state problem which cannot be controlled by private industry. We, therefore, would favor appropriate amendments to the Federal Food, Drug, and Cosmetic Act and the Controlled Substances Act which specifically prohibit the manufacture, distribution, and trafficking in "controlled drug look-alikes" in any product form.

Additionally, we feel that a Federal Government agency should receive appropriations and a mandate to develop and implement a public awareness program which is aimed at the problem in its broadest sense. We believe that the pharmaceutical trade associations and manufacturers would willingly participate in such an effort. Many health care firms, such as Warner-Lambert, have underway uncoordinated efforts in this area of concern. Our youth are sophisticated, and these programs must be designed, in our opinion, to appeal to their intellectual and emotional level. They should be marketed through the various media, such as radio, TV and newspapers, in a manner similar to new product introductions, sporting events, and the like. The development of this type of program needs complete cooperation of not only government and industry, but also the educational community. We would be willing to increase Warner-Lambert's activities through a centralized effort.

We thank the Select Committee for giving us this oppoortunity to express our views on this national problem. We commend your efforts to seek viable solutions to the dangers which "controlled drug look-alikes" represent to the public, and especially the youth of our nation.

Thank you.

DRAFT—STATEMENT AND CONTINUING GUARANTEE

The purchaser, —— (hereinafter called Purchaser), hereby certifies to the supplier, Capsugel Division of Parke-Davis (hereinafter called Supplier), a wholly-owned subsidiary of the Warner-Lambert Company, Morris Plains, New Jersey, that no capsules heretofore or hereafter obtained from the Supplier are or will be knowingly use by Purchaser or, to Purchaser's knowledge, by its distributes, in the produciton, encapsulation, packaging or marketing of any product which is in violation of any Federal, state or local law, including but not limited to the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. 801 et seq.), the Controlled Substances Act (21 U.S.C. 801 et seq.) or any corresponding law of any state or local authority. It is further warranted by Purchaser that no capsules heretofore or hereafter obtained from Supplier are or will be knowingly used by Purchaser or to Purchaser's knowledge, by its customers or distributees, in the production, encapsulation, packaging or marketing of any illegitimate products, or any legitimate product, which is likely to confuse, mislead or be falsely misrepresented to any person as being the same as or similar in content to a Controlled Substance. This statement and guarantee shall be continuing and shall remain in force until revoked in writing by Purchaser.

The purchaser, hereby authorizes Supplier to provide a copy of this document to governmental departments or agencies having jurisdiction to determine whether or not said capsules, and the products of which they are a part, are being utilized in conformity with applicable federal, state and local laws. Purchaser acknowledges that the providing of this document to such a governmental body by Supplier shall be considered to be a submission by Purchaser directly to that governmental body; and that such governmental body may rely upon the contents hereof.

The purchaser: Name. ——. Title. ——.

VIEWS ON WARNER-LAMBERT DRAFT "STATEMENT AND CONTINUING GUARANTEE"

At the request of Warner-Lambert Company, the Select Committee circulated copies of Warner-Lambert's draft "Statement and Continuing Guarantee" proposal to a number of Federal agencies and the Congressional Research Service for comment. Committee staff also provided comments to Warner-Lambert on the proposal. Those views follow.

THE POSTMASTER GENERAL,
Washington, D.C. July 9, 1982.

Hon. LEO C. ZEFERETTI,
Chairman, Select Committee on Narcotics Abuse and Control, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your letter of June 18, concerning a proposal that the Warner-Lambert Company believes would be of assistance in controlling the manufacture of look-alike drugs. The proposal would require customers of the company's Capsugel Division to sign guarantees that capsules would not be used in violation of Federal, state or local food and drug laws or to make look-alike products. The company believes that acting contrary to the terms of the guarantee would be a basis for criminal prosection under several Federal statutes including Title 18, United States Code, Section 1341, the Mail Fraud Statute.

The Chief Postal Inspector advises it is doubtful that a violation of the terms of the proposed guarantee would constitute a substantive addition to the evidence necessary to support a criminal prosecution under the Mail Fraud Statute. Whether the proposed guarantee would be of value in prosecutions or enforcement action under the other laws cited in your letter are questions that the agencies or departments involved would have to answer.

Quite apart from whether Warner-Lambert's suggestion would facilitate prosecutions, they are to be commended for voluntarily undertaking a program that will make it more difficult for the promoters of look-alike drugs to ply their trade. If all of the suppliers of gelatin capsules were required to obtain this type of continuing guarantee from their customers, it might be of value in identifying questionable users of the products.

As you know the Postal Service has brought a number of actions under the False Representation Statute, Title 39 United States Code, Section 3005, against look-alike suppliers. Given the limited investigative tools at our disposal, these efforts have achieved a considerable degree of success.

Enclosed for your information is a copy of my letter of December 2, 1981, to Congressman Bill Ford containing the views of the Postal Service on H.R. 3973.

Sincerely,

WILLIAM F. BOLGER.

Enclosure.

CONGRESSIONAL RESEARCH SERVICE,
THE LIBRARY OF CONGRESS,
Washington, D.C. July 14, 1982.

To: House Select Committee on Narcotics Abuse and Control Attention: George Gilbert.
From: American Law Division.
Subject: Questions Re: Manufacturer's Proposal Not to Sell Capsules Without a Signed Continuing Guarantee that the Buyer Will Not Market the Capsules in Such a Way as to Imitate Controlled Substances.

This is in response to your request that the American Law Division review a capsule manufacturer's proposal to request customers to sign a statement that capsules to be purchased would not be used to violate the food, drug, and controlled substances laws or to make look-alike products and to provide copies of those statements to government agencies as direct submissions of the customer. One of the reasons such a measure has been proposed is the possibility that the signing of the

statement in combination with its being filed with the federal government would give rise to a possible criminal action for violating certain federal laws.

CRIMINAL LIABILITY

Presently, it would appear that the schemes described: holding out noncontrolled substances to be controlled substances and selling them on that basis could be reached under the following types of criminal statues:

(1) state fraud laws and statutes outlawing the obtaining of property by false pretenses;

(2) state look-alike drug laws, in the few jurisdictions having such laws;[1]

(3) the federal mail fraud and wire fraud statues, 18 U.S.C. §§ 1341 and 1343, provided the scheme to obtain money involved use of the mails or wire communications; and

(4) The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 801, et seq., provided the manufacturer has failed to meet the requirements of the act in terms of preclearance when required, labeling, etc.

The possibility that the existence of the statement would create additional criminal liability, however, is speculative.

Section 1001 of titles 18 prohibits, inter alia, knowing and willful falsification of a writing in a matter within the jurisdiction of a federal agency. It also prohibits the knowing use of a false writing in any such matters. Five elements are necessary for a conviction: (1) statement, (2) falsity, (3) materiality, (4) specific intent, and (5) agency jurisdiction. *United States* v. *Godwin* 566 F. 2d 975 (5th Cir. 1978). The proposed continuing guarantee contains a statement of present intention with regard to future intent or future actions. Although proof might be difficult, if it could be shown that a person with the intention of producing look-alikes signed such a guarantee, there would be a false statement within the terms of the act.

There is, moreover, a more serious question as to whether the statement in the guarantee pertains to a matter within the jurisdiction of a federal agency for purposes of the act. Even though the courts have held that for purposes of this act the term, "jurisdiction," should be given a broad meaning, *United States* v. *Lambert*, 501 F. 2d 943 (5th Cir. 1974), they have held it to require that the agency have the power to act upon information when received. *United States* v. *Adler*, 380 F. 2d 917 (2d Cir. 1967), cert. denied 389 U.S. 1006 (1968). The matter in question, fraudulent mispresentation of the contents of the capsules, could apparently be within the jurisdiction of serveral federal agencies, including the Federal Trade Commission, the Food and Drug Administration and the Justice Department, provided certain other elements—for example, use of the mails, false labeling or misbranding—existed. The existence or non-existence of deceptive advertising would be cognizable in an FTC administrative procedure without regard to the continuing guarantee. However, it would seem unlikely that a manufacturer could transform what is presently a civil regulatory proceeding on the issue of whether there is an unfair trade practice into a criminal action for violation of the false statement statute simply by requiring a customer to make a warranty to the effect that goods purchased will not be used for illegal purposes. If the FTC required such a guarantee, however, there could be a criminal prosecution.

Another statute that has been suggested as a potential source of criminal liability were these continuing guarantee statements required by the manufacturer of capsules is the Racketeer Influenced Corrupt Organizations statute, 18 U.S.C. §§ 1961–1968. For a prosecution under this statute a pattern of racketeering activity must be alleged. That, in turn, is defined in terms of predicate offenses, among which are: "any act or threat involving murder, kidnapping, gambling, arson, robbery, bribery, extortion, or dealing in narcotics or other dangerous drugs, which is chargeable under State law and punishable by imprisonment for more than one year;" "any act which is indictable under . . . section 1341 [of title 18] (relating to mail fraud), section 1343 (relating to wire fraud) . . .;" and "the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in narcotic or dangerous drugs, punishable under any law of the United States." 18 U.S.C. § 1961. It would not appear that the continuing guarantee would add anything in the nature of jurisdiction to the RICO provision: if the predicate act is indictable under state or

[1] See 1981 Ark. Laws 209, amending Ark. Stat. §82-2601; 1981 Conn. Legis Service, Pub. Act. No. 81-199, amending Conn. Gen. Stat. §19.473; Del. Code Ann., tit. 16 §4752A; 1981 Ind. Laws 125, amending Ind. Code §35-48-4; 1981 Kans. Laws, ch. 140, 1981 La. Laws 1087, amending La. Rev. Stat., tit. 40 §971.1; 1981 Md. Laws, ch. 628; 1981 Okla. Laws, ch. 229; 1981 S.D. Laws, ch. 183.

federal law relating to dangerous drugs, two instances of such an act would be cognizable under RICO. If it were not, the continuing guarantee would not appear to confer federal RICO jurisdiction.

Since the kinds of transactions that have been described, passing off legal drugs as controlled substances and advertising non-controlled substances as containing controlled substances, do not appear to be reachable under federal drug laws, the only possible RICO prosecution would have to rest on violation of state drug laws. In states, such as Maryland,[2] that have laws regulating the sale of look-alike drugs there may be sufficient grounds for a federal prosecution under RICO. On the other hand since such laws specifically relate to substances not classified as dangerous controlled substances, violation of their provisions may not be violation of state laws regulating dangerous drugs, as required under RICO. Under the RICO mail and wire fraud predicate offenses, the continuing guarantee would seem to add nothing that would be dispositive on the issue of jurisdiction. If there were jurisdiction for either of these offenses without the continuing guarantee, there would be no need to show the continuing guarantee. If, however, the suggestion is that the mail fraud statute could be used if the prosecution could show that X used the continuing guarantee to obtain capsules through the mail from Y company and then sold the capsules in violation of the continuing guarantee, it might be possible that there could be a successful prosecution under 18 U.S.C. § 1341 (the mail fraud statute.). The essential elements of the offense would be (1) forming a scheme to defraud and (2) using the mails to further that scheme. *United States* v. *Freeman*, 619 F. 2d 1112 (5th Cir. 1980), cert. denied 450 U.S. 910 (1981). It would not seem likely that the scheme to defraud could be couched in terms of obtaining the capsules on the false representation of intent, but rather it would have to be expressed in terms of using the capsules in combination with a noncontrolled substance to obtain money by fraudulently representing the combination to be a dangerous controlled substance, and using the mail in furtherance of that scheme.

RESTRAINT OF TRADE

The continuing guarantee concept also raises the question whether there would be any restraint of trade problems if a company refuses to sell to a potential customer who refuses to sign the continuing guarantee.[3] Without more information on the general market structure of the capsule drugs business, we can only provide general guidance on the principles of restraint of trade laws. Under §762 of 4 Restatement Torts, the common law principles on refusal to deal are stated:

"One who causes intended or unintended harm to another merely by refusing to enter into a business relation with the other or to continue a business relation terminable at his will is not liable for the harm if the refusal is not (a) a breach of the actor's duty to the other arising from the nature of the actor's business or from a legislative enactment, or (b) a means of accomplishing an illegal effect upon competition, or (c) part of a concerted refusal by a combination of persons of which he is a member."

The basic federal antitrust law that deals with restraint of trade, section 1 of the Sherman Act, 15 U.S.C. § 1, maintains these principles. It prohibits inter alia, "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several states. . . ." The courts in construing this section, when the conduct in question is not a per se violation of the Sherman Act, such as price fixing agreements, have adopted a rule of reason:

"Applying the rule of reason to the construction of the statute, it was held in the *Standard Oil Case* that as the words "restraint of trade" at common law and in the law of this country at the time of the adoption of the Anti-trust Act only embraced acts or contracts or agreements or combinations which operated to the prejudice of the public interests by unduly restricting competition or unduly obstructing the due course of trade or which, either because of their inherent nature or effect or because of the evident purpose of the acts, etc., injuriously restrained trade, that the words as used in the statute were designed to have and did have but a like significance. It was therefore pointed out that the statute did not forbid or restrain the power to

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[2] 1981 Laws of Md, ch. 628, prohibits the distribution, attempted distribution, and possession with intent to distribute noncontrolled substances intended for use or distribution as a controlled dangerous substance.

[3] You have also asked if there would be a restraint of trade question if a federal agency encouraged a company to secure such continuing guarantees. Since the restraint of trade laws do not seek to regulate government activity and since we have found no grounds for a restraint of trade issue in the general situation you have described, the action of a government agency in encouraging the use of the continuing guaranty would not seem to raise one.

make normal and usual contracts to further trade by resorting to all normal methods, whether by agreement or otherwise, to accomplish such purpose. In other words, it was held, not that acts which the statute prohibited could be removed from the control of its prohibitions by a finding that they were reasonable, but that the duty to interpret which inevitably arose from the general character of the term restraint of trade required that the words restraint of trade should be given a meaning which would not destroy the individual right to contract and render difficult if not impossible any movement of trade in the channels of interstate commerce—the free movement of which it was the purpose of the statute to protect."—*United States* v. *American Tobacco Co.*, 221 U.S. 106, 188–189 (1911).

On the issue of individual selection of customers the leading cases are *Great Atlantic & Pacific Tea Co.* v. *Cream of Wheat*, 227 F. 46 (2d Cir. 1915) and *United States* v. *Colgate & Co.*, 250 U.S. 300 (1919). In *Cream of Wheat* the issue was whether a manufacturer could legally require as a condition of sale that the buyer be a wholesaler, rather than a retailer or an ultimate customer. In upholding the right of the manufacturer the court said:

"Before the Sherman Act it was the law that a trader might reject the offer of a proposing buyer, for any reason that appealed to him; it might be that he did not like the other's business methods, or because he had some personal difference with him, political, racial or social. That was purely his own affair, which nobody else had any concern. Neither the Sherman Act, nor any decision of the Supreme Court construing the same, nor the Clayton Act, has changed the law in this particular. We have not yet reached the stage where the selection of a trader's customers is made for him by the government."—227 F. 46, at 49.

In *Colgate*, the Supreme Court made the following comment on the right of a manufacturer to Select customers:

"The purpose of the Sherman Act is to prohibit monopolies, contracts and combinations which probably would unduly interfere with the free exercise of their rights by those engaged, or who wish to engage, in trade and commerce—in a word to preserve the right of freedom to trade. In the absence of any purpose to create or maintain a monopoly, the act does not restrict the long recognized right of trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal. And, of course, he may announce in advance the circumstances under which he will refuse to sell."—250 U.S. 300, at 307.

It would, thus, appear that the general situation you have decribed would not rise to the level of restraint of trade, which is not to say that a manufacturer could not in a given circumstance under specific factual conditions be found liable for restraint of trade in using such a continuing guaranty. Since we have no knowledge of the market and of the types of buyers for this product, we cannot speculate on what may be a remotely possible situation in which a showing of restraint of trade could be made.

SUGGESTION AS TO DRAFTING OF THE CONTINUING GUARANTEE

There could perhaps be clarification of the obligation of the buyer not to produce or cause to be produced knowingly the various types of products mentioned (rather than guaranteeing that the capsules will not be knowingly used by the buyer and others who may perhaps not be in his control) for the prohibited purpose. We recommend you consider the following language:

"That the purchaser shall not knowingly use capsules purchased from the supplier to: (1) produce any product in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321 et seq., and the Controlled Substances Act 21 U.S.C. §§ 801, et seq. or any state or local controlled substances or food and drug law (2) produce or cause to be produced a product, likely to confuse, mislead or be falsely represented to any person as being the same as similar in content to a controlled drug product of another manufacture, and to hold out that product as being the same or similar to a controlled drug of another manufacture or to sell it with the intent that others believe it to be such a controlled drug product."

We hope this information is helpful to you.

M. MAUREEN MURPHY, *Legislative Attorney.*

FEDERAL TRADE COMMISSION,
Washington, D.C., July 21, 1982.

Hon. LEO C. ZEFERETTI,
Chairman, Select Committee on Narcotics Abuse and Control,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Chairman James C. Miller III has asked us to respond to your letter of June 18, 1982, which requested comments on Warner-Lambert's proposed continuing guarantee. Our comments reflect only the views of the Bureaus of Competiton and Consumer Protection and do not necessarily reflect the views of the Commission or any individual commissioner. Also, because the Warner-Lambert proposal is preliminary, our comments are general in nature.

As you, we are greatly concerned about the problem of "look-alike" drugs, and have been working with other federal agencies to develop a coordinated strategy for dealing with this problem. Action by responsible members of the drug industry may well represent one of the best alternatives for enforcement. Therefore, we welcome this opportunity to comment on the Warner-Lambert proposal.

A continuing guarantee such as that proposed by Warner-Lambert could provide a valuable deterrent and a means by which federal and state officials could identify violators. However, we have several concerns with the current proposal.

As you are aware, look-alikes are only one part of a growing problem. The Inter-Agency Task Force is becoming increasingly concerned that look-alikes are being supplanted by non-look-alike mood-altering drugs sold in new and unapproved combinations. These products may be sold in capsules such as those marketed by Warner-Lambert. Failure to include these new products in the guarantee may only accelerate the shift away from look-alikes and forfeit an opportunity to address this issue. Warner-Lambert should consider expanding its proposed guarantee to prohibit the use of its capsules for the production of drugs marketed solely for mood-alteration purposes that are not approved by the Food and Drug Administration.

Second, we are seriously concerned about the potential impact of the guarantee, as presently drafted, on the sales of generic drugs. The Commission has been in the forefront in encouraging the passage of state generic substitution laws as part of its effort to promote competition in the health care field.[1] Almost all the states have enacted such laws.

Our concern is that the guarantee may deny the use of certain capsule colors to generic drug manufacturers who now have a protected right to use those colors. The capsule colors in question are those used by patients, doctors, and hospital personnel to identify the chemical composition of the drug contained within a capsule, rather than to identify the manufacturer of the drug. Without access to such colors, generic drug manufacturers could be unable to compete effectively with branded drug manufacturers and, consequently, consumer drug prices could rise.

The right of generic drug manufacturers to use functional capsule colors that are not primarily identified with any particular drug manufacturer was recently reaffirmed by the Supreme Court in the case of *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 50 U.S.L.W. 4592 (June 1, 1982). The Supreme Court specifically rejected the contention that simply because generic drug manufacturers "could reasonably anticipate" that some unscrupulous pharmacies might "palm off" the generic drug as a branded drug, the generic drug manufacturers would be liable for contributing to such a "palming off" if they used the same capsule colors as the branded drug manufacturer. Id. at 4595 n.13, 4597.

The second sentence of Warner-Lambert's proposed continuing guarantee provides that a drug manufacturer cannot use Warner-Lambert capsules to produce a drug product "which is likely to * * * be misrepresented to any person as being the same as * * * a controlled drug product of another manufacturer." This clause could restrict a generic manufacturer's use of a functional capsule color merely because an unscrupulous third party might "palm off" a generic drug as a branded drug. In effect, this could give a branded drug manufacturer the exclusive use of a functional capsule color in the very circumstances under which the Supreme Court has denied exclusivity. Accordingly, we recommend that the second sentence be redrafted so as to ensure that the continuing guarnatee will not reduce the ability of generic drug manufacturers to compete effectively.[2]

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[1] FTC Report on Drug Product Selection, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. (1979).

[2] By discussing only this particular competitive concern, we do not mean to suggest that there are necessarily no other such concerns. For example Warner-Lambert's subsidiary, Parke,

Continued

Finally, it may be possible for a manufacturer of look-alike drugs to avoid the restrictions of the continuing guarantee simply by purchasing from an intermediary. To address this problem, we suggest that the guarantee be expanded to cover the knowing resale by the original purchaser for any of the purposes prohibited by the guarantee.

In conclusion, we appreciate the opportunity to share our concerns with you and to continue our efforts to identify useful means for dealing with this troubling problem.

Sincerely,

THOMAS J. CAMPBELL,
Director, Bureau of Competition.
TIMOTHY J. MURIS,
Director, Bureau of Consumer Protection.

DEPARTMENT OF HEALTH & HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION,
Rockville Md., July 29, 1982

Hon. LEO C. ZEFERETTI,
Chairman, Select Committee on Narcotics Abuse and Control, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: I am writing in response to your letter of June 18, concerning a Warner-Lambert proposal which might help control the distribution of over-the-counter (OTC) look-alike drug products.

I am pleased that Warner-Lambert has taken such an interest in the look-alike problem and commend them for their efforts in this area. We have no objections to their proposal and certainly agree that this type of action might help curtail the distribution of capsules used in the manufacturing of look-alike drugs.

Although we believe the proposal might be a useful deterrent to customers of Warner-Lambert, our legal counsel informs me that the companies involved in the illegitimate use of capsules would not incur additional liability under the provisions of the Federal Food, Drug, and Cosmetic Act from violating the guarantee made to Warner-Lambert. Furthermore, in order to find an 18 U.S.C Section 1001 violation, it is necessary that the matter be ". . . within the jurisdiction of any department or agency . . ." It is not likely that the guarantee between Warner-Lambert and their customer firms falls within the scope of the provision.

I hope that the above information is useful. If I can be of further assistance, please let me know.

Sincerely yours,

ARTHUR HULL HAYES, Jr., M.D.,
Commissioner of Food and Drugs.

U.S. HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL,
Washington, D.C., August 4, 1982.

Mr. CHARLES E. LENTS,
Counsel, Regulatory Affairs, Warner-Lambert Co.,
Morris Plains, N.J.

DEAR MR. LENTS: This is in reply to your request, pursuant to our meeting of June 4, 1982, and your letters of June 3 and June 21, 1982, for comments on Warner-Lambert's "Continuing Guarantee" proposal concerning sales of empty gelatin capsules that may be used to produce so-called "look-alike" drugs.

As you know, copies of your initial draft "Continuing Guarantee" form along with your proposed letter of explanation to capsule customers were sent to Federal agencies and the American Law Division/Congressional Research Service for comment. George Gilbert of our staff has forwarded to you copies of the written comments we have received from the Postal Service and the American Law Division of CRS. The views of the Federal Trade Commission and the Food and Drug Administration are enclosed.

Although we have not yet received written comments from the Drug Enforcement Administration, we have discussed your proposal with the agency informally. In general, they applaud Warner-Lambert's proposal as a potentially valuable deter-

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Davis, and Company, and Eli Lilly and Company are subject to an antitrust consent decree which governs their marketing of drug capsules and related machinery. United States v. Parke, Davis and Co., 1951 Trade Reg. Rep. (CCH) ¶ 62,914 (E.D. Mich. 1951).

rent to look-alike manufacturers and would welcome your voluntary use of the "Continuing Guarantee" with your capsule customers. They seriously question, however, whether a knowing violation of the Guarantee by a capsule customer, without the established commission of proscribed acts, would constitute evidence of a criminal violation under Federal law. Similar doubts are raised in the Postal Service, CRS and FDA comments. We will send you DEA's written views as soon as we receive them.

We share the questions that have been raised as to whether the willful breach of a "Continuing Guarantee," without more, is legally sufficient to give rise to Federal criminal liability. Placing aside the issue of criminality, however, it is our view that the principal purpose of the Guarantee is to make clear to prospective buyers that Warner-Lambert will not supply capsules except under the conditions spelled out in the Guarantee. To this end, we believe use of the "Continuing Guarantee" would significantly deter unscrupulous manufacturers from using capsules to make look-alike products and would increase the difficulty of producing look-alike substances (or products that do not specifically imitate the appearance of controlled drugs but may be advertised and sold as containing controlled substances). Futhermore, even though a knowing violation of a "Continuing Guarantee" may not constitute evidence of a Federal crime, such information provided to Federal authorities could be helpful in identifying persons or firms who may be violating Federal law. We commend Warner-Lambert for developing the "Continuing Guarantee" concept and encourage you to implement it with your capsule customers.

With respect to the "Continuing Guarantee" form itself, we offer the following suggestions (based on the revised draft included in your letter of June 21, 1982).

First, we recommend that the Guarantee include a preamble spelling out the reasons why Warner-Lambert is requiring its capsule customers to execute the form and the consequences of failing to sign or knowingly violating the terms of the Guarantee. This preamble could note the growing trade in over-the-counter drugs made to imitate the appearance of, and often represented as, commonly abused controlled substances; your desire to prevent the use of Warner-Lambert capsules in such products; and the responsiblity you feel not only to protect the reputation of your company and the responsible pharmaceutical industry but also to protect the public from the dangers inherent in these products. The preamble could close by stating that in furtherance of these goals, Warner-Lambert will only sell capsules to customers who sign the "Continuing Guarantee" and that the knowing violation of any of the Guarantee's terms will result in the immediate termination of Warner-Lambert's obligation to supply capsules under any existing contracts with the customer and the refusal to fill new capsule orders in the future. The preamble could also state that breach of the Guarantee may subject the violator to criminal prosecution.

While the preamble would not be a substitute for the explanatory letter to Capsugel customers, it would allow the "Continuing Guarantee" form to stand on its own by giving clear notice of both the concerns that have motivated Warner-Lambert to require such assurances and the consequences that will result if the Guarantee is not signed or its terms not honored. This unequivocal statement of your intentions should serve the Guarantee's primary purpose—to prevent use of your capsules in ways that are illegal or damaging to Warner-Lambert and the public—and at the same time project Warner-Lambert from reprisal on restraint of trade or other grounds.

Second, we suggest that the language in the first paragraph of the "Continuing Guarantee" setting forth the Federal, state and local laws the customer warrants not to violate be made inclusive instead of exclusive. This can be accomplished by adding the words "any Federal, state or local law, including but not limited to" after the words "in violation of" in the first sentence. Since the Postal Service has taken action against look-alike distributors on the grounds that their advertisements constitute false representations in violation of 39 U.S.C. 3005, and since such products and the claims made for them may violate other Federal laws as well (e.g., the Federal Trade Commission Act), it would be counterproductive to limit the language of the Guarantee to the two Federal statutes and corresponding state and local laws currently cited in your proposed form.

Third, we call attention specifically to the Federal Trade Commission's concern about the impact of the proposed "Continuing Guarantee" on generic drug manufacturers. We agree that the "Guarantee" should be redrafted so as not to reduce the ability of generic drug manufacturers to compete effectively.

I hope these comments will be helpful to you. Please contact us if we can be of further assistance.

Sincerely,

PATRICK L. CARPENTIER, *Chief Counsel.*

U.S. DEPARTMENT OF JUSTICE,
OFFICE OF LEGISLATIVE AFFAIRS,
Washington, D.C., September 20, 1982.

Hon. LEO C. ZEFERETTI,
Chairman, Select Committee on Narcotics Abuse and Control, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your letter of June 18, 1982, in which you requested the views of the Department of Justice regarding Warner-Lambert's proposal to require customers of their Capsugel Division to sign a continuing guarantee not to manufacture imitation controlled substances or "look-alikes."

The Department of Justice has been aware of this proposal since a meeting with Warner-Lambert has been aware of this proposal since a meeting with Warner-Lambert officials on May 4, 1982. Mr. Gene Haislip, the Drug Enforcement Administration's Deputy Assistant Administrator, Office of Diversion Control, discussed this proposal with attendees of an interagency meeting on look-alikes on May 20, 1982. Those present (representatives of the Drug Enforcement Administration, Food and Drug Administration, Federal Trade Commission, United States Postal Service, Internal Revenue Service and National Institute on Drug Abuse) found no substantial problems with Warner-Lambert's proposal as a mechanism for the company to deal with the use of their capsules for look-alikes. Mr. Haislip sent a letter to Warner-Lambert on behalf of the interagency government group on look-alikes, encouraging them to take whatever measures they felt were appropriate to alleviate the problem.

We feel that the Warner-Lambert proposal may have some value as a deterrent to those purchasers wishing to produce look-alikes. However, there appears to be no legal force behind the continuing guarantee in terms of subjecting the purchasers to criminal prosecution under federal statutes for violating the agreement. Because capsules themselves are not subject to the provisions of the Controlled Substances Act (CSA), a violation of this agreement would not constitute a prosecutable violation of the CSA. Also, it is highly unlikely that 18 U.S.C. 1001 (false or fraudulent statements or entries) as it relates to the CSA, could be used to prosecute violators of the continuing guarantee.

With respect to antitrust considerations, we suggest that the language be clarified by referring to "noncontrolled products" rather than "products" in line 6 of the draft proposal. As to the Department's enforcement intentions in this area, private parties may request, as in other areas of antitrust law, a written statement of the Department's present enforcement intentions with respect to a proposed course of conduct, pursuant to the "Business Review Procedure" (28 C.F.R. § 50.6). A request for a business review letter must be submitted in writing to the Assistant Attorney General, Antitrust Division, Department of Justice, Washington, D.C. 20530.

In summary, Warner-Lambert's suggestion has merit as a deterrent to capsule customers making look-alikes. Additionally, it may serve as a tool to enable their Capsule Division to differentiate legitimate capsule orders from questionable ones. However, there appears to be no basis for the Federal prosecution of look-alike producers who violate the continuing guarantee under the CSA or 18 U.S.C. 1001 as it applies to the CSA.

Please be assured that the Department is continuing to work closely with other federal agencies as well as local governments and industry representatives to control the look-alike problem. In the meantime, I appreciate your deep interest in this issue and hope the above comments are responsive to your inquiry.

Sincerely,

ROBERT A. MCCONNELL,
Assistant Attorney General.

[The final version of the Warner-Lambert Capsule Continuing Guarantee appears on p. 126.]

PREPARED STATEMENT BY JOSEPH P. HILE, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, we welcome the opportunity to participate in this important hearing on "look-alike" drugs and the public health problem which they represent.

Last October, in Jersey City, New Jersey, we discussed with you the rapid growth of the over-the-counter (OTC) look-alike phenomenon and the public health and law enforcement problems associated with it. We reviewed the role that the Food and Drug Administration (FDA) felt it could play to reduce the traffic in OTC look-alikes and the seizures of OTC look-alike products and the equipment used in their manufacture that FDA had already undertaken against nine major manufacturers of these drugs. I am pleased to provide you with an update of our activities since that hearing and to describe our future actions in response to recent trends in the illegitimate OTC trade.

UPDATE OF SEPTEMBER 1981 SEIZURES

In late 1980 and early 1981, a substantial increase in OTC look-alike traffic, coupled with reports of adverse reactions and the growing law enforcement problems that look-alikes were causing, convinced FDA that it should initiate whatever actions it could legally take to reduce this new public health problem. The Agency reviewed its statutory authority and began to search for manufacturers of OTC look-alikes. Our investigation turned up the nine manufacturers which were the subject of the September 1981 seizures.

In these actions, United States Marshals accompanied by FDA representatives seized capsules and tablets which mimicked both the "trade dress" (size, color and shape) and the markings of products containing ingredients regulated under the Controlled Substances Act. Approximately fifteen million filled dosage units, many ready for sale, and more than twenty million empty capsules already imprinted with counterfeit markings were seized. In addition, punches, dyes, offset rollers as well as major pieces of manufacturing equipment valued at approximately one million dollars were seized.

These seizures were based on the counterfeit and seizure provisions of the Federal Food, Drug, and Cosmetic Act. Aside from defining a counterfeit drug, the Act prohibits counterfeiting, and permits seizures of the drugs, their containers and the equipment used in their manufacture. Essentially, a counterfeit drug is one which bears a trademark or other identifying mark of another drug—and thus falsely purports to be that other drug.

I am pleased to inform you that five of the nine cases have now been settled by consent decrees. The terms of the decrees vary somewhat but the majority contain injunctive language prohibiting the manfacture, sale, distribution or holding of any drug which is a counterfeit as well as any drug which is an "Imitation" under the Act. In the remaining four cases settlement is being actively pursued. In all of the cases where consent decrees have been signed, the decrees order the destruction of the finished drugs, capsules, dyes and punches.

Criminal prosecution has not been precluded in any of these cases. In fact, we have begun to consider the existing evidence to determine the feasibility of prosecutions. This activity has been interrupted by the new drug activities I will discuss later and by other high priority resource intensive activities. However, before we could prosecute we would be required by the Act to provide an opportunity for those persons against whom criminal proceedings were contemplated to appear before the Agency to discuss why they should not be prosecuted.

UPDATE OF OTHER ACTIVITIES

In addition to following up on the nine seizures, FDA also has ben involved in look-alike enforcement activities in Florida and Wisconsin, has sent letters to manufacturers regarding cocaine look-alike products, and has engaged in an extensive investigation of suspected look-alike distributors.

Last summer, approximately 600 pounds of tablets marked "LEMMON 714" resembling Quaalude, the brand name for methaqualone, a depressant controlled substance, were discovered near an unmarked airplane in Florida by the Florida Game and Fresh Water Commission. Analysis of the tablets by the Drug Enforcement Administration (DEA) and FDA revealed that the tablets contained either small amounts of an antihistamine or no drug substance at all. The Florida State officials and the DEA were unable to take any action and requested FDA to assist them to assure that these tablets were not distributed. In November 1981, seizure of these

tablets was accomplished. It appears that the airplane came from outside the United States.

In a separate development, our Minneapolis District office received information that an OTC look-alike manufacturer had established a manufacturing plant on a farm in Wisconsin. An investigation culminated in a search of the premises under a warrant. Evidence obtained during the investigations indicated the facility may have been involved in the manufacturing of counterfeit products. However, recent reinspection reveals the firm has gone out of business with no evidence of continuing manufacturing activity.

While these two incidents represent isolated cases with little probable impact on the overall OTC look-alike problem, they demonstrate FDA's interest in pursuing any lead as it arises as well as the channel of communication existing between FDA and DEA on OTC look-alike matters.

FDA has also been receiving reports indicating that prescription local anesthetics such as lidocaine, procaine and tetracaine are being used as substitutes for street cocaine. The Agency has received reports of three deaths associated with injecting or sniffing these substitute white powders. The main dangers of these substitutes are that they can collapse blood vessels, depress heart muscle strength and cause low blood pressure. In July, FDA sent letters to the anesthetic manufacturers warning them that their products were being abused and asking them to initiate stringent controls over distribution to assure that the anesthetics are offered for sale only to legally authorized firms. If the problem is not resolved by the manufacturers, FDA will consider what further regulatory action is necessary to control the manufacture and distribution of these cocaine substitutes.

DISTRIBUTORS INVESTIGATION

Following the September 1981 seizure of drugs and equipment at the manufacturer's level, FDA proceeded to develop a strategy against distributors—the next link along the OTC chain. Last December, all district offices were requested to conduct investigations of distributors suspected to be actively engaged in the distribution of OTC look-alike drugs. FDA investigators acting as potential customers were instructed to obtain all representations and suggestions made by the distributors that their products could be "passed off" as controlled substances. In the opinion of the Agency, such evidence could be necessary to take advantage of the "imitation" drug provision of the Act—and thus expand the scope of authority being brought to bear against OTC look-alikes.

As I described earlier, the seizures against the manufacturers were based on our "counterfeit" authority, which requires the mimicking of another drug's identifying mark. This authority is not applicable against an OTC look-alike that copies the size, shape, and color of a controlled substance but does not mimic the markings. In such circumstances, the "imitation" provision could apply where there is evidence that the look-alikes are "passed off" as controlled substances. The drug imitation section of the statute has no legislative history nor are there any cases interpreting it. Evidence of "passing-off" or other evidence of illicit marketing is essential because without it we would be interpreting our statute as prohibiting any two drugs from resembling one another in appearance. While such an interpretation may have some appeal against OTC look-alikes, there are trade-mark and perhaps due process problems which would probably render such an interpretation unworkable and, on balance, undesirable.

FDA's assessment of the information uncovered during the investigation of distributors led the Agency to conclude that imitation charges could be brought against several of the approximately 40 distributors who were under investigation. The Act contains an injunction authority over imitation drugs that is lacking for counterfeit drugs. The Agency concluded that counterfeit charges were available against almost all the distributors. However, we also now anticipate bringing a third authority to bear against the distributors in the form of an unapproved new drug charge under the Act. Toward this end, we will publish a notice in the Federal Register within the next week that confirms the Agency policy that drugs containing the triple combination of phenylpropanolamine, ephedrine sulfate and caffeine are now regarded as "new drugs" and thus require an application to FDA for marketing approval. Appropriate regulatory action as a follow-up to the Federal Register notice is planned.

This use of the new drug authority is a recent development which I will discuss in detail. As background, I would first like to review various trends in the OTC look-alike trade since the seizures which, in total, have led us toward this step.

TRENDS SINCE THE SEPTEMBER 1981 SEIZURES

Our adverse reaction reporting systems have reported only one death attributed to OTC look-alike drugs since the seizures against the nine manufacturers last September. Before the seizures, we were aware of 12 deaths. We cannot establish a cause and effect relationship between this drop-off and our enforcement activities; in fact, the failure to report deaths may be attributable to a mistaken identification of the drug by either the user or reporter due to the success of the deception involved.

We have also seen a reduction in OTC look-alike advertising in some drug related magazines. While we would like to be able to report to you that this phenomenon reflects a reduction in the traffic of these drugs, we feel it is more likely that the distribution of these products is moving away from open channels of commerce and is acquiring a classic, drug abuse character.

We can report with some certainty that the seizures have reduced the traffic in counterfeits which mimic the markings of manufacturers of controlled substances. We believe that in order to evade FDA enforcement action, however manufacturers are reacting to the seizures by moving away from counterfeiting and toward OTC combinations which do not physically resemble controlled substances. Non-look-alike products appear to be on the upswing.

Unfortunately, the manufacturers have correctly recognized that the effectiveness of our counterfeit and imitation authorities decreases as physical resemblance to controlled substances becomes more tenuous. However, the predominant formulation in these products is now a triple combination of caffeine, ephedrine (a decongestant), and phenylpropanolamine (an appetite suppressant and nasal decongestant); thus many of these drugs are reachable regardless of appearance because this combination of ingredients is subject to our "new drug" authority.

THE NEW DRUG AUTHORITY

For our purposes, the term "new drug" refers to recognition rather than age. As defined by the Act, a new drug is one which is not generally recognized by experts as safe and effective for use under conditions stated on the labeling. A new drug is thus prohibited from interstate commerce until it receives marketing approval from the Food and Drug Administration.

Individually, the three ingredients in the triple combination may not be new drugs. They have been on the market in OTC products for decades, either alone or in combination with other ingredients. Thus individually, and in some combinations, they have fallen under the purview of FDA's ongoing over-the-counter drug review—a ten year effort to determine the safety and efficacy of the more than 700 active ingredients in some 300,000 OTC products sold in this country. Panels of experts involved in the OTC review already have recommended to FDA that all three ingredients individually are safe and effective for use in a variety of OTC products for at least one indication.

For a considerable period of time it was unclear whether the three ingredients as found in the OTC look-alikes existed together in a triple combination in some legitimate OTC products. If they did, they would fall under the purview of the OTC review and be potentially exempt from enforcement action until the review's analysis was complete. However, no OTC products containing the triple combination have been found aside from the drug abuse products at issue. FDA has therefore determined that the triple combination is outside the OTC review and should be regarded as a new drug because it is not generally recognized by experts as safe and effective for use as described in the labeling. Case law establishes that such recognition must be based on published reports of adequate and well-controlled clinical investigations.

FDA recently issued regulatory letters to 14 manufacturers of triple combination products informing them that these products are unapproved new drugs and that their shipment in interstate commerce is a violation of the law. The letters requested that the manufacturers advise FDA of steps taken to correct all violations associated with these products. We are preparing to take the same step with the distributors.

While we are optimistic that our actions will eradicate the triple combination and have significant impact on the immediate availability of illegitimate OTC products, we know also that the new drug charge responds only to one aspect of an evolving problem. We have reason to believe that manufacturers are already reacting by deleting one of the three ingredients and thereby manufacturing a product which falls within the purview of the OTC review and actually possesses a rational medical use. To the extent that such a product does not physically resemble a controlled substance and is generally recognized by experts as safe and effective when used in ac-

cordance with its labeling, its abuse after being removed from a properly labeled package would present a new and challenging enforcement problem.

One suggested solution has been the scheduling of the triple combination, or perhaps a dual combination, under the Controlled Substances Act. It is our understanding, based on discussions with DEA counsel, that the scheduling criteria in the Controlled Substances Act (CSA) apply to individual ingredients rather than finished drug products. As that statute is currently written, there is a legal bar to scheduling any combination of ingredients unless one or more of the ingredients qualifies for regulation under the CSA. We are currently considering whether it is reasonable to believe that phenylpropanolamine could meet the criteria for scheduling. If phenylpropanolamine were to be scheduled, combinations containing phenylpropanolamine would also be scheduled under the Controlled Substances Act.

CONCLUSION

As the OTC look-alike trade modifies its behavior to avoid violations of the FD&C Act, it may become increasingly more difficult for FDA to act against these manufacturers and distributors. The regulatory scope of the Food and Drug Administration is broad but it does not extend into the area of street abuse which would require undercover investigations by FDA employees outside the conventional channels of commerce.

FDA can and will continue to contribute toward the reduction of the OTC look-alike drug trade through its counterfeit and imitation authorities for OTC products that physically resemble controlled substances, and through its new drug authority when certain criteria are met regarding the ingredients. It is true that legal questions about the counterfeit authority are being litigated now and that there is presently no precedent for the use of the imitation authority. Experience may thus reveal the need to consider modifying these authorities in ways we cannot presently ascertain.

Mr. Chairman, this concludes my formal statement. I will be happy to try to answer any other questions that you or other Committee members may have.

Department of Health and Human Services Views on Senate-Passed Legislation Relating to Look-Alike Drugs

Secretary of Health and Human Services,
Washington, D.C., December 3, 1982.

Hon. Thomas P. O'Neill,
Speaker of the House of Representatives,
Washington, DC

Dear Mr. Speaker: There is pending before the House of Representatives H.R. 3963, as amended by the Senate, a bill "To amend the Contract Services for Drug Dependent Federal Offenders Act of 1978 to extend the periods for which funds are authorized to be appropriated." We take this opportunity to inform you of our views on that bill, and specifically on section 303.

In summary, we must oppose enactment of section 303(a), which would amend the Federal Food, Drug, and Cosmetic Act (FFD&C Act) to create criminal penalties for manufacture and distribution of "look-alike" drugs, because this provision would require undercover activities in the area of clandestine "street" drug abuse which would be well beyond the established mission and expertise of the Food and Drug Administration (FDA), which administers that statute.

We support enactment of section 303(b), which would amend the FFD&C Act to authorize FDA to obtain injunctions against the manufacture and distribution of counterfeit drugs. With respect to the merits of the remainder of the bill, we defer to the Department of Justice.

Section 303(a) of H.R. 3963 would amend the FFD&C Act to establish criminal sanctions, including fines and imprisonment, on the manufacture and distribution of imitation controlled substances. The bill defines an imitation controlled substance as any substance other than a controlled substance or prescription drug which is marketed, sold, or distributed to encourage recreational drug use or abuse or any similar nonmedical use, and which either would by representation or appearance lead a reasonable person to believe that it is a controlled substance, or purports to act like a controlled substance. The amendment would also make it unlawful to place an advertisement in a newspaper or other publication or in a handbill with reasonable knowledge that the advertisement promotes the distribution of imitation controlled substances. Section 303(b) would repeal an existing provision of the FFD&C Act which precludes FDA from obtaining injunctions against the manufacture and distribution of counterfeit drugs and the making, selling, or concealing of the equipment used to make counterfeit drugs.

These proposed amendments would provide a federal authority specifically aimed at stemming the traffic in what has come to be known as over-the-counter (OTC) look-alike drugs. Although OTC look-alikes contain non-prescription drugs which are available over the counter, they mimic, through size, color, shape, and markings, various prescription products that contain substances of abuse, such as amphetamines, barbiturates, and tranquilizers.

The manner in which these products are manufactured and distributed presents special enforcement problems for the federal government. Because look-alike drugs do not contain controlled substances, but only look as if they do, they have not been regulated under the Controlled Substances Act of 1970 (CSA) and related statutes administered by the Justice Department's Drug Enforcement Administration (DEA), the federal agency mainly responsible for regulating drug abuse at the "street" level. On the other hand, since FDA's regulatory activities involving drugs traditionally concentrate on the manufacturing level, the street abuse aspects of the problem are outside of that agency's normal enforcement activities.

Both because of the established mission of FDA, and because of the nature of the look-alike drug problem, we believe that it would be inappropriate and ineffective to assign to that Agency responsibility for enforcing the new criminal provisions that would be created by this legislative proposal. FDA's primary responsibility with respect to drug products is to regulate their manufacture and distribution to ensure that they are safe and effective for legitimate purposes, and that their labeling is not false or misleading. The main focus of its laws and the programs designed to implement them is on legitimate products in open channels of commerce.

For a period in its history, FDA exercised authority over illegal traffic in certain classes of drugs, through its Bureau of Drug Abuse Control. However, under a 1968 reorganization, the Bureau of Drug Abuse Control and the Treasury Department's Bureau of Narcotics were merged to form the Bureau of Narcotics and Dangerous Drugs in the Department of Justice. This agency has now become the DEA, whose authority was expanded and systematized by the Controlled Substances Act of 1970. With these changes in authority, FDA's primary role in connection with the regulation of drug abuse became limited to providing scientific support to the Assistant Secretary for Health, and in turn to DEA, for scheduling of drugs of abuse under the CSA.

Nonetheless, FDA has been able to bring its existing statutory authorities to bear against manufacturers and distributors of OTC look-alike and related drugs because, for the most part, these products have been openly manufactured, distributed and advertised. The "counterfeit" drug provision of its statute is available against OTC products that copy the trademark or identifying mark of another firm's products containing controlled substances. This authority was utilized in 1981 against manufacturers of OTC look-alikes to seize millions of capsules as well as the equipment used to make them. There is also an "imitation" drug provision which is available against unmarked OTC products which resemble the size, shape, and color of controlled substances where there is evidence that the imitation is falsely represented as a controlled substance. However, evidence of such misrepresentation is difficult to obtain at the manufacturer or distributor level.

Section 303(b) of H.R. 3963 would strengthen FDA's authority to control the traffic in counterfeit drugs, by removing the present prohibition in the FFD&C Act on obtaining injunctions against the manufacture and distribution of counterfeit drugs and the making, selling, or concealing of the equipment used to make counterfeit drugs. Since a seizure is directed only at the specific items which are seized, FDA must initiate a new seizure action when a manufacturer replaces seized equipment or produces more counterfeit drugs. An injunction, in contrast, prohibits a manufacturer or distributor from continuing the same activities; where a manufacturer or distributor persists FDA may proceed against him for contempt of court and violation of an injunction. The availability of both sanctions would give FDA greater flexibility to tailor its enforcement activities to the circumstances of individual cases.

As manufacturers have recognized, however, the effectiveness of the "counterfeit" and "imitation" provisions decreases as the physical resemblance of drug products to controlled substances decreases. There is now a trend away from products which physically resemble controlled substances toward "legal stimulants"—typically combinations of OTC ingredients with an overall stimulant effect—which appear to be acquiring markets of their own. At least one of these combinations may currently be sold over the counter when properly labeled.

Under its authority to approve new drugs, FDA has been able to act against the predominant combination of caffeine, ephedrine (a decongestant) and phenylpropanolamine (an appetite suppressant and nasal decongestant). FDA has declared that

products containing this combination lack the general recognition of experts as safe and effective when used in accordance with their labeling, and are therefore prohibited in interstate commerce until approved by FDA. This action should eradicate this triple combination of ingredients and significantly reduce the immediate availability of illegitimate OTC products; however, it responds to only one facet of this evolving problem. Manufacturers can react by producing drugs containing OTC ingredients which, individually or in combination, actually possess rational medical uses.

To the extent that these products containing OTC drugs do not physically resemble controlled substances and are generally recognized by experts as safe and effective when used in accordance with their labeling, their abuse after being removed from properly labeled packages would present an enforcement problem beyond the established mission of FDA. FDA's primary responsibility is, and should remain, to regulate legitimate products in open channels of commerce to ensure that they are safe, effective, and not misleadingly labeled. The amendment proposed by section 303(b) of H.R. 3963 would enhance FDA's ability to carry out this mission. However, the amendment proposed by section 303(a) of that bill would require enforcement activities outside FDA's mission and expertise.

In order to enforce the criminal provisions proposed by section 303(a) of H.R. 3963, it would be necessary to establish that the manufacturer or distributor of a product intended that the product be used not for legitimate purposes but instead for recreation. The labeling and advertising might not provide direct evidence of this actual purpose. Labeling can easily be brought into compliance with FDA labeling requirements for OTC products. Advertising today typically claims only that the product is a nonprescription stimulant or sleep aid. Thus, the primary evidence available to prove violation of these provisions would generally be representations made by street vendors of the drugs, in sales to the ultimate consumers. Similar evidence would also be necessary under the provision which prohibits advertising imitation controlled substances. In short, in order to obtain the evidence needed to enforce these provisions, it would be necessary to engage in undercover investigations of street sales of these products, an activity in which FDA has no expertise.

In summary, we believe that FDA's role in the regulation of look-alike drugs should remain within the scope of its basic mission; we support the enactment of injunction authority with respect to counterfeit drugs, which would strengthen FDA's ability to carry out its responsibilities. We strongly oppose expansion of FDA's mission into the type of investigation and enforcement activities that would be required by section 303(a).

For the foregoing reasons, we oppose enactment of section 303(a) of H.R. 3963, but support enactment of section 303(b) of that bill. We defer to the Department of Justice on the merits of the remainder of the bill.

We are advised by the Office of Management and Budget that there is no objection to the transmission of this report from the standpoint of the Administration's program.

Sincerely,

DICK SCHWEIKER, *Secretary.*

PREPARED STATEMENT OF GENE HAISLIP, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, U.S DEPARTMENT OF JUSTICE

LOOK-ALIKES

Chairman Zeferetti and Members of the House Select Committee on Narcotics Abuse and Control: Since last October when I testified before you regarding the production and distribution of look-alike drugs, much has been accomplished in the effort to control this contemptible activity. From DEA's perspective, the initiatives taken within the past year have had a significant impact on the look-alike drug problem. The growth of this phenomenon has been arrested and, in a number of areas, there has been a substantial decline in the manufacture and distribution of look-alikes. I hasten to add, however, that the problem still exists. In the testimony which follows, I will briefly characterize the look-alike problem as it exists today and then describe the efforts taken by DEA and their impact.

Nature of the look-alike problem

Look-alikes are tablets, capsules, or other substances containing noncontrolled, over-the-counter (OTC) ingredients, which closely resemble well-known, highly abused controlled drug products. Look-alike stimulants mimic the appearance of amphetamine or amphetamine-like products and generally contain one or more of the

following OTC drugs: caffeine, ephedrine, pseudoephedrine and phenylpropanolamine. The depressant look-alikes mimic the appearance of sedative or hypnotic products such as Quaalude, Valium and Librium, and generally contain combinations of the following OTC ingredients: acetaminophen, salicylamide, doxylamine and chlorpheniramine.

Although the individual ingredients used to manufacture look-alikes are legitimately used as nasal decongestants, analgesics, or for the relief of cold, allergy or asthma symptoms, they can also produce various stimulant or depressant effects.

Unfortunately, the look-alike user is lured into believing these pills will produce effects equal to those of the controlled substances they mimic. In an effort to attain the desired effect, look-alike users may ingest quantities of pills large enough to cause serious injury. Reactions to these stimulants and depressants may be mild, such as nervousness, insomnia, or drowsiness; however, more serious reactions may occur such as sharp rises in blood pressure, cerebral hemorrhage or temporary psychotic episodes.

There is also a considerable danger to young persons who are accustomed to taking look-alikes and who unknowingly ingest equal quantities of actual controlled substances. There is a much greater likelihood of an adverse reaction in these cases, particularly when depressant substances are involved.

The medical hazards due to the look-alike phenomenon are further increased by the fact that health care professionals in emergency rooms, poison control centers and drug abuse clinics are experiencing problems in determining proper treatment for individuals due to the misrepresentation of look-alikes to the user.

In response to this growing problem a new category was established in the Drug Abuse Warning Network (DAWN) reporting system in 1981. During the first reporting year, 38 emergency room episodes were directly attributed to look-alikes. All but 5 episodes involved drugs reportedly obtained by street buys, the manner in which other abused substances are obtained. It is noteworthy that the Food and Drug Administration has documented at least 12 deaths due to the use of look-alikes.

The dangers of look-alike drugs are not limited to their direct health effects. Time, money and manpower have been expended by law enforcement personnel to buy or seize these substances only to find out that no prosecutable crime has been committeed. As a result, police in some jurisdictions have ceased buying or seizing pills purported to be controlled stimulants or depressants, which makes it easier for drug dealers to peddle the real controlled substance. Perhaps worst of all, the advertising, distribution and use of look-alike drugs give the impression of societal acceptance of drug use for recreational purposes. Advertisements which depict look-alikes as safe and completely legal undermine drug prevention programs and counteract the many drug abuse education programs supported by government, industry and community organizations. The use of psychoactive substances for mood alterations—even in the form of look-alike—if condoned, can only add to our national drug abuse problem.

Another unfortunate aspect of this situation is the exploitation of our nation's youth for profit. Look-alike advertisements are aimed at and distributed primarily to teenagers. In mid-1981, it was estimated that up to 30 million doses of look-alikes were manufactured weekly and distributed by well over 200 wholesalers in the United States. These look-alikes were sold primarily in bottles of 1000 for $18–$150 per bottle. In turn, they were sold on the street for $0.50–$1.50 per pill, yielding profile of up to $1000–$1500 for each 1000 capsules sold.

I would like to mention another novel, yet closely related, facet of this drug abuse problem—that of "look-alike" pills which do not resemble controlled drug products. As a result of recent enforcement actions against look-alike substances, some producers have changed their product lines to include tablets, and to a lesser extent, capsules, which contain the same OTC ingredients as the look-alikes but do not mimic any of the highly abused controlled drug products. Given such names as "U-Zoom," "Hi-Risers," and "20–20's," these products are promoted as being legal and marketed in the same unscrupulous manner as look-alikes. In a related manner, other producers, motivated by the lure of huge profits and the popularity of cocaine, are marketing cocaine substitutes with product names such as Supercaine, Summacaine, Pseudocaine, Ultracaine, Superiorcaine, Base-O-Caine and Toot. These substances contain noncontrolled drugs such as lidocaine, procaine, tetracaine and dyclonine which have local anesthetic propertiee similar to cocaine, but these ingredients may cause collapsed blood vessels, depressed heart muscle strength and reduced blood pressure. To date, the FDA has received reports of three deaths associated with the use of cocaine substitutes.

DEA initiatives

DEA has no specific jurisdiction over look-alike products under the Controlled Substances Act (CSA) because the pills contain only noncontrolled substances. However, DEA has a responsibility to combat drug abuse and considers the problem of look-alike drugs to be a facet of drug abuse. The distribution and sale of look-alikes, encourages and contributes to the profiteering from drug abuse. Therefore, the program described to you last October to help curb the look-alike problem has been initiated. The main activities we have undertaken and an assessment of their impact to date are as follows:

1. Drafting of a Model Act for concerned States to adopt

In November 1981, DEA drafted and distributed to the states a Model limitation Controlled Substances Act. A reviewed version was distributed in February 1982. The Model Act makes it unlawful for anyone to manufacture, distribute, possess or advertise an imitation controlled substance. An imitation controlled substance is defined as a noncontrolled substance which by overall dosage unit appearance or by representation made, would lead a reasonable person to believe that the substance is a controlled substance. At this time, 28 states have passed some form of legislation against look-alikes; another 17 states have legislation pending. An informal survey conducted by DEA's Office of Diversion Control in March 1982 showed that the 10 states reporting a decrease in the availability of look-alikes have look-alike legislation or are enforcing existing pharmacy regulations. Of the states responding to the survey, only 3 noted an increase in this abuse problem since mid-1981. Delaware, the first state to enact look-alike legislation, noted a dramatic decrease in availability. The impact of state look-alike legislation is encouraging. It is essential that more states adopt some form of look-alike legislation and, more importantly, that these laws are enforced and violators prosecuted.

2. Preparation of documentation describing the look-alike problem, its dangers and its effects, for use in support of the Model Act

Information packages have been distributed to DEA field offices for use by personnel who are requested to provide information or testimony in support of state look-alike legislation. DEA representatives have made presentations concerning look-alikes to state legislatures, professional organizations, law enforcement personnel and parent and community groups in an effort to encourage their support of state look-alike legislation.

3. Fostering intergovernmental agency cooperation and providing active support to other agency efforts

Because no single Federal agency has clear-cut jurisdiction over the look-alike problem, it is imperative that the relevant Federal agencies coordinate their efforts against look-alike drugs. DEA has taken the initiative to establish interagency governmental groups at both the policymaking and working levels. Representatives of the Drug Enforcement Administration, the Food and Drug Administration, the Federal Trade Commission, U.S. Postal Service, the Internal Revenue Service, and the National Institute on Drug Abuse meet periodically to discuss the dynamics of the look-alike problem, to identify changing trends in distribution and abuse patterns, and to report on each agency's activity or need for interagency support. Additionally, DEA has supported the efforts of the U.S. Postal Service and the FDA by supplying intelligence and by providing laboratory analyses and expert testimony in court against look-alike manufacturers and distributors.

An excellent example of successful interagency cooperation is the case of Frye Pharmaceuticals, Inc., a CSA registrant and manufacturer of look-alikes. In September 1981, FDA seized look-alike pills and equipment from Frye Pharmaceuticals, Inc. of Birmingham, Alabama, for violating the counterfeit statute of the Food, Drug and Cosmetic Act. Frye Pharmaceuticals, Inc. entered into a consent agreement which permanently enjoined them from manufacturing, distributing and promoting counterfeit drugs. A subsequent DEA investigation of Mr. Bill R. Frye, owner of the company, revealed he continued to sell counterfeit capsules identical to those seized by FDA. Based on this information, FDA requested that Mr. Frye be held in contempt of court.

4. Enlisting the support and/or action of the legitimate pharmaceutical industry

In an effort to limit the availability of capsules used to manufacture look-alikes, DEA asked the three domestic capsule manufacturers to voluntarily refuse orders to suspected look-alike manufacturers. This effort appears to be somewhat successful in that the availability of the popular black and yellow capsules is more limited now than last year. Industry cooperation has also resulted in a lawsuit filed by one large

legitimate manufacturer of controlled substances against a look-alike producer for trade-mark infringement.

The combined actions of DEA, FDA and the U.S. Postal Service in conjunction with those of states, the indusry, and community groups, have had an impact on the look-alike problem. In some cases, companies have been driven out of business or have been forced to drastically alter their operations. However, there remains a significant core of manufacturers and distributors who find the profits lucrative enough to be willing to change tactics and/or fight to remain in business.

More needs to be done at all levels of government. Continued efforts by states to enact and effectively utilize look-alike legislation will help. I applaud the actions taken by the FDA and U.S. Postal Service. They must continue. It appears that the common elements in the look-alike problem are the misleading advertising, marketing and promotion of these products. Perhaps, a strategy at the Federal level, utilizing the experience and expertise of the appropriate Federal agencies can be formulated to address the problem on grounds of deceptive marketing and advertising practices which have an effect on the public health.

I can assure you that DEA will continue to work closely with other Federal agencies, local governments and industry to arrive at a satisfactory and effective solution to the problem of look-alike drugs.

I thank you for this opportunity to express DEA's views on this matter and for the Committee's continuing interest in the effort to control this drug abuse problem.

PREPARED STATEMENT OF AMANDA B. PEDERSEN, DEPUTY DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION

Mr. Chairman and members of this committee, I am Amanda B. Pedersen, Deputy Director of the Bureau of Consumer Protection at the Federal Trade Commission. Thank you for this opportunity to present my views on the problem of "lookalike" drugs. These remarks reflect my own views as a member of the Federal Trade Commission staff, and do not represent official Commission policy.

The problem of so-called "lookalike" drugs continues to be of grave concern. By the term "looklike" drugs, I refer to drugs that mimic the shape and color of controlled substances, as well as drugs offered for unapproved mood-altering purposes and sold as though they were controlled substances. These drugs appear to be marketed broadly, and, to the extent that Commission staff has been able to monitor advertising for these drugs, it has sometimes found explicit claims of mood enhancement.

The growth of this trade is especially troubling as it appears to be successfully targeted to young people. Current figures indicate that the health hazards associated with drug abuse through the use of lookalikes are significant.

Hearings conducted by this Select Committee last October focused attention on the serious nature of this problem. Since that time, the staff of the Commission, along with other federal agencies, has continued to explore possible avenues for effectively controlling these products. We are participating in an Inter-Agency Task Force with representatives of the Food and Drug Administration, the Drug Enforcement Administration, the Postal Service, and the Internal Revenue Service, who meet periodically to share information and develop strategies.

In attempting to address the lookalike problem, it is important to understand the way in which lookalike drugs are produced and distributed. There are basically four links to the distribution chain. At the top, there are companies that manufacture the gelatinous capsules, the vast majority of which are used for legitimate purposes. Also at this level are the manufacturers of the various chemical compounds that are the raw ingredients. The second tier is the filler or encapsulator companies that combine the raw ingredients and place them in capsules. The third level is the wholesalers that promote and sell the product in bulk, generally to other smaller distributors and occasionally to individuals for their own use. Finally, there are retailers who sell the product to ultimate customers. Although we are unable to estimate how many companies or individuals are involved at the third and fourth tiers, we believe that they are numerous and difficult to identify.

In my view, drug abuse through the use of lookalikes is not primarily an advertising or marketing problem. The fundamental problem with lookalikes, if these drugs are as harmful as we understand them to be, is that they are available at all. Questions such as whether or under what circumstances these products should be manufactured, or whether to impose an outright ban on the sale of these products, may not be best resolved by the Federal Trade Commission. Nonetheless, we are continuing to examine what actions the Commission could take.

The Commission's authority to prohibit deceptive advertising may not be applicable under these circumstances. Lookalikes are usually promoted through informal or underground networks. To the extent that there is advertising, it often focuses on the mood-altering characteristics of these drugs—claims that are probably not deceptive.

Even if the FTC successfully brought a deceptive advertising case, the impact would be limited. If the Commission were able to prohibit all advertising, the most likely result would be that sellers would simply alter their method of marketing. If it were able to prevent specific claims, sellers would easily change their advertisements. Finally, if disclosures were mandated regarding health hazards or illegality, they would probably have little effect in deterring purchase, and might even enhance the desirability of the products.

As the Committee is aware, the staff of the Division of Advertising Practices has recommended a full-phase investigation to assess the application of the FTC's unfairness authority to companies that manufacture lookalike products in their final form. The memorandum has now been reviewed by the Associate Director and was recently sent to the Bureau for final decision.

The unfairness authority was articulated by the Commission in its March 9, 1982 letter to the Senate Commerce Committee. The Commision considers that a violation exists if (1) there is substantial injury; (2) consumers could not reasonably avoid the harm; and (3) the injury is not offset by other benefits. The standards for meeting these requirements are still developing and we will examine these issues in detail before making a final recommendation to the Commission.

Additionally, there are numerous other problems that need further exploration. For example, successful litigation would require resolving difficult scientific and pharmacological issues. Most importantly, the Food and Drug Administration itself, on which we rely heavily in health matters, has not yet issued a determination on the safety or efficiacy of these products for the purpose for which they are being promoted.

As with a deception case, I am seriously concerned with our ability to mandate an effective remedy. A product ban may be the only meaningful remedy, and it is unclear whether the Commission's authority provides for such relief. Further, the Commission's traditional action, a Section 5 complaint, involves a lengthy administrative proceeding that may not be sufficiently timely to address this evergrowing problem. Although the Commission may seek injunctions in federal court under certain circumstances, the Commission ordinarily utilizes that remedy only in situations where the law violations has been clearly established.

While there are many questions regarding the Commission's direct intervention, the staff is encouraged by a recent proposal by one of the manufacturers of the gelatinous capsules that are used in the production of many lookalikes. This proposal represents, in my opinion, a potentially significant breakthrough. Under this proposal, purchasers of the capsules would have to enter a continuing gurarantee not to use capsules for the production of lookalike substances.

Only a few companies manufacture the gelatinous capsules and it appears prohibitively costly for other smaller concerns to begin manufacture. Therefore, responsibile action by these manufacturers may offer an effective deterrent to the production of lookalikes and provide an effective deterrent to the production of lookalikes and provide a means of identifying violators. In operating under this proposal, companies could refer refusals to sign and violations of the agreement to enforcement agencies, as well as refuse future sales to those who either do not sign or violate the guarantee. Thus, it might be possible to limit the supply of capsules for use in producing lookalike drugs. A further advantage of this proposal is that it could be implemented without delay.

As we noted in our July 21, 1982 letter to Chairman Zeferetti, the current proposal could be strengthened to address not only the problem of lookalike drugs, but also the increasingly serious issue of non-lookalike mood-altering drugs. We must also caution the Committee, however, that the proposal, as presently drafted, raises certain serious antitrust concerns. Nothing contained in the guarantee should be subject to an interpretation that would inhibit the manufacture or sale of generic drugs.

Many of the issues in need of further consideration with regard to the proposed guarantee are ones in which the Commission possesses substantial expertise. Because of the real benefits that might accrue from such a program, we would be pleased to work with this Committee and the manufacturing companies on improvement of the current proposal in order to achieve its intended purpose and avoid certain antitrust problems that are described in detail in our letter with Chairman Zeferetti.

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In conclusion, let me emphasize my deep concern about look-alike drugs. The Bureau staff has not yet reached a final recommendation, and, of course, the Commission must also consider these issues before any action could be taken. We intend to continue to evaluate our own opportunities for action as well as to work with other state and federal agencies. In attempting to direct resources where they will have the greatest impact, we again encourage continued efforts by the industry and reiterate our willingness to advise on current proposals.

Thank you for inviting me to testify. I would be pleased to answer any questions you may have.

PREPARED STATEMENT OF DAVID W. MADDEN, POSTAL INSPECTOR IN CHARGE

Mr. Chairman, my name is David W. Madden, and I am the Postal Inspector in charge of the Cincinnati Division. Formerly, I was the Postal Inspector in Charge of the Special Investigations Division, which conducts the investigations of mail order sales of look-alike drugs. On October 26, 1981, former Assistant Chief Postal Inspector William T. Murphy and I testified at your hearing in Jersey City, New Jersey, on the Postal Service's efforts to curtail the mail order sale and distribution of look-alike drugs. Today, I would like to provide you the current status of our efforts.

During our testimony on October 26, we mentioned that the Postal Service had filed false representation complaints under Title 39, U.S. Code, Section 3005, against 11 companies who were using the U.S. mail to sell look-alike drugs. These companies ceased their mail order operations as a result of Consent Agreements or False Representation Orders which directed the return of their mail to the sender. Since that hearing, the Postal Service has filed false representation complaints against 30 additional companies. These companies have also ceased the mail order sale of look-alike drugs.

Recently, we completed investigations relating to 18 other companies which are promoting the mail order sale and distribution of look-alike drugs. These cases have been presented to the Postal Service Law Department to consider whether false representation complaints should be filed.

The sale and distribution of look-alike drugs by mail order appear to have been curtailed as a result of the civil enforcement actions which I have mentioned. Nevertheless, most of the major promoters are circumventing the False Representation Orders and Consent Agreements by continuing their activities outside the mails. Their current advertisements tell prospective customers that only telephone orders will be accepted and that payment must be by credit card, bank wire, or United Parcel Service C.O.D. These procedures remove the orders and monies from the U.S. mail, thereby rendering any Mail Stop Order remedy under current law ineffective.

We will continue to investigate any company seeking orders or monies from false and misleading advertisements of look-alike drugs. However, to the extent they are able to distribute their products and receive monies outside the mails, then their activities are beyond the administrative authority of the Postal Service to deal with them. The bill S. 1407, which has passed the Senate and is now pending in the House, would seek to deal with this kind of situation by authorizing the Government to seek civil penalties in court against anyone who resumes a false representation scheme in interstate commerce [illegible] outside the mails after a valid Mail Stop Order has been issued.

We are often asked whether look-alike drugs are safe to use. Information received from other law enforcement officials, public officials, and the news media (both television and newspapers), has attributed at least 16 deaths and one case of paralysis to the use of these drugs.

Expert testimony obtained by the Postal Service for its administrative enforcement actions has shown that look-alike drugs are a serious safety and health hazard. The full potential of the adverse effects caused by the combination of caffeine, phenylpropanolamine (PPA), and ephedrine has never been established. Based on this expert testimony, the Postal Service has included the safety and health hazards of the products in the false representation complaints filed against promoters of look-alike drugs.

At the request of your staff, we have made a preliminary review of Senate bills S. 2735 and S. 2736. Senate bill 2735 proposes an amendment to Title 39, U.S. Code, Section 3001. The amendment, in essence, would make any matter which reasonably could be interpreted or construed as a drug-abuse advertisement or a shipment of imitation controlled substances in response to such advertisement nonmailable for purposes of the administrative remedies administered by the Postal Service. Senate

bill 2736 would make the manufacture or distribution of imitation controlled substances, except for authorized purposes, a criminal offense.

The Postal Service has not yet had sufficient time to complete its review of this legislation, which was introduced in July.

Mr. Chairman, I want to thank you for the opportunity to appear before this committee. I will be happy to answer any questions you may have.

NEW YORK STATE LAW ON LOOK-ALIKE DRUGS—APPROVED JULY 13, 1982

An act to amend the public health law, in relation to imitation controlled substances

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. The public health law is amended by adding a new section thirty-three hundred eighty-three to read as follows:

§ 3383. Imitation controlled substances. 1. For purposes of this section, the following terms shall have the following meanings:

a. "Manufacture" means the production, preparation, compounding, tableting, processing, encapsulating, packaging, repackaging, labeling or relabeling of an imitation controlled substance.

b. "Markings" means a simulated trademark, trade name, imprinting or other mark, or likeness thereof, of the manufacturer, distributor or dispenser of a controlled substance or a simulated code number or symbol or likeness thereof identifying a controlled substance or combination of such substances.

c. "Imitation controlled substance" means a substance, other than a prescription drug, that is not a controlled substance, which by dosage unit appearance, including color, shape and size and by a representation is represented bo be a controlled substance. Evidence of representations that the substance is a controlled substance may include but is not limited to oral or written representations by the manufacturer or seller, as the case may be, about the substance with regard to:

(i) its price, nature, use or effect as a controlled substance; or

(ii) its packaging in a manner normally used for illicit controlled substances; or

(iii) markings on the substance.

2. It shall be unlawful for any person to manufacture, sell or possess with the intent to sell, an imitation controlled substance.

3. It shall be unlawful for any person to possess or use any punch, die, plate, stone or any other equipment in order to print, imprint, or reproduce the trademark, trade name or other identifying mark, imprint or device of another or any likeness of any of the foregoing upon any substance or container or labeling thereof with intent to manufacture an imitation controlled substance.

4. No liability shall be imposed by virtue of this section on any person licensed pursuant to article one hundred thirty-one of the education law or licensed under this article who manufactures, distributed, sells, prescribes, dispenses or possesses an imitation controlled substance for use as a placebo or for use in clinical research conducted pursuant to the federal food, drug and cosmetic act.

5. Nothing in this section shall apply to a noncontrolled substance that was initially introduced into commerce prior to the initial introduction into commerce of the controlled substance which it is alleged to imitate.

6. In any prosecution under this section it shall be necessary to prove that the imitation controlled substance was represented to be a controlled substance; however, it shall not be a defense to a prosecution under this section that the accused believed the imitation controlled substance to be a controlled substance.

7. A violation of subdivision two or three of this section shall be a class A misdemeanor. A violation of subdivision two or three of this section by a person previously convicted of a violation of this section within the preceding five years shall be a class E felony.

8. If any provision or part of this section or application thereof is held invalid, the invalidity shall not affect other provisions, parts or applications of this section which can be given effect without the invalid provisions or application, and to this end the provisions of this section are severable.

§ 2. Section thirty-three hundred eighty-seven of such law, as added by chapter eight hundred seventy-eight of the laws of nineteen hundred seventy-two, the section heading and subdivisicn one as amended by chapter five hundred forty-seven of the laws of nineteen hundred eighty-one and subdivision three as amended by chapter eight hundred forty-three of the laws of nineteen hundred eighty, is amended to read as follows:

§ 3387. Seizure and forfeiture of controlled substances, imitation controlled substances and official New York state prescription forms; disposition. 1. any controlled substance or imitation controlled substance which has been manufactured, distributed, dispensed or acquired in violation of this article, or the lawful possession of which cannot be immediately ascertained, and any official New York state prescription form which has been printed, distributed or acquired in violation of this article or the lawful possession of which cannot be immediately ascertained are hereby delcared to be public nuisances and may be seized by a peace officer, acting pursuant to his special duties, or a police officer and shall be forfeited, and disposed of as follows:

(a) except as in this section otherwise provided, the commissioner, the court or magistrate having jurisdiction shall order such controlled substance or imitation controlled substance forfeited or destroyed. A record of the quantity and nature of the substance, of the place where said substance was seized, and of the time, place and manner of destruction, shall be kept, and a return under oath, reporting said destruction, shall be made to the person ordering such destruction by the officer who destroys them;

(b) upon written application by the commissioner, the court or magistrate by whom the forfeiture of controlled substances or imitation controlled substances has been decreed may order the delivery of any of them, except substances listed in schedule I of section thirty-three hundred six, to such commissioner for distribution or destruction, as hereinafter provided;

(c) upon application by any hospital within this state, not operated for private gain, the commissioner may in his discretion deliver any controlled substance or imitation controlled substance that has come into his custody by authority of this section to the applicants for medicinal use;

(d) the commissioner may from time to time deliver excess stocks of controlled substances or imitation controlled substances to the Bureau or shall destroy the same;

(e) controlled substances or imitation controlled substances which are excess or undesired by persons lawfully possessing the same may be disposed of by express prepaid shipment to the "State Department of Health, Narcotic Control Bureau, Albany, New York," or by delivery to an authorized narcotic control representative of the department;

(f) official New York state prescription forms which have been seized as provided by this section shall be disposed of by express prepaid shipment to the "State Department of Health, Bureau of Prescription Analysis, Albany, New York," or by delivery to an authorized narcotic control representative of the department.

2. The commissioner shall keep a full and complete record of all controlled substances or imitation controlled substances received and of all controlled substances or imitation controlled substances disposed of, showing the exact kinds, quantities and forms of such substances; the persons from whom received and to whom delivered; by whose authority received, delivered and destroyed; and the dates of the receipt, disposal or destruction. This record shall be open to inspection by all federal or state officers charged with the enforcement of federal and state laws relating to controlled substances or imitation controlled substances.

3. Any raw material product, container or equipment of any kind which is used, or intended for use, in manufacturing, distributing, dispensing or administering a controlled substance or imitation controlled substance in violation of this article shall be seized by any peace officer, acting pursuant to his special duties, or police officer and forfeited in the same manner as property subject to seizure and forfeiture pursuant to section thirty-three hundred eighty-eight of this article, except that such property shall not be retained for use by any official.

§ 3. This act shall take effect on the first day of September next succeeding the date on which it shall have become a law.

FOLLOW-UP QUESTIONS TO FEDERAL AGENCIES AND RESPONSES

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL,
Washington, D.C., September 1, 1982.

Mr. GENE R. HAISLIP,
Director, Office of Compliance and Regulatory Affairs,
Drug Enforcement Administration, Washington, D.C.

DEAR MR. HAISLIP: Thank you for testifying during the Select Committee's follow-up hearing on Look-Alike Drugs on August 12, 1982. Enclosed are some follow-up questions we request that you answer so that the hearing record may be complete.

We appreciate your cooperation, and would like to stress the importance of your prompt reply.

Sincerely yours,

LEO C. ZEFERETTI, *Chairman.*

Enclosure.

QUESTIONS FOR DEA

1. To what extent is organized crime involved in the look-alike drug business?

2. In *U.S.* v *Gesauldi*, 660 F. 2d 59 (2d Cir., 1981), the court upheld the defendants' conviction under section 403(a)(5) of the Controlled Substances Act (21 U.S.C. 843(a)(5)) for possession of counterfeit drug dies even though the defendants apparently intended only to make "look-alike" methaqualone tablets, not counterfeit controlled substances.

a. To what extent has DEA attempted to use the authority of that case against other look-alike manufacturers?

b. What plans does DEA have to use this authority in the future?

3. Could the DEA Model Imitation Controlled Substances Act (as amended, February, 1982), which was distributed to states in February, 1982, be adapted for use at the Federal level?

a. Would it deal effectively with the emerging problem of "look-alike" pills which do not resemble controlled drug products?

b. Will you please provide the Committee with a copy of your Model Act?

4. What additional resources would DEA need if given jurisdiction to enforce a new Federal law prohibiting the manufacture, distribution or possession (with intent to distribute) of look-alike drugs?

5. How many states have enacted laws to stem the look-alike trade to date? How many of these laws resemble the DEA Model Act?

6. Have any state laws patterned after the DEA Model Act been challenged in court? With what results?

7. In light of the continued and apparently increasing abuse of OTC products containing phenylpropanolamine (PPA) and also in light of FDA's current review of whether PPA meets the criteria for scheduling under the Controlled Substances Act, is DEA reassessing whether PPA should be controlled?

8. a. What kinds of local action is being taken by community groups as a result of DEA's addressing various interest groups in order to raise public awareness of the look-alike problem?

b. What are the effects of this local action?

9. a. To what extent is the look-alike problem being monitored by the DEA field offices?

b. What factors do the field offices look to in order to determine the extent and existence of look-alike drugs in their areas?

c. Are there areas which are not surveyed effectively by those field offices? If so, what would be needed to improve data collection?

10. Do you have any information as to how large the industry is in terms of:

a. Annual sales?

b. Number of manufacturers?

c. Number of distributors?

d. Have these numbers changed over the last year?

11. a. What contributions and recommendations do you plan to make to the interagency task force formed to coordinate efforts to combat the look-alike problem?

b. What initiatives have the task force begun and are being planned?

c. Will you please submit for our hearing record a copy of any report or summary of any proceedings by the task force to date?

U.S. DEPARTMENT OF JUSTICE,
DRUG ENFORCEMENT ADMINISTRATION,
Washington, D.C., September 30, 1982.

Hon. LEO C. ZEFERETTI,
Chairman, Select Committee on Narcotics Abuse and Control,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Thank you for providing the opportunity for Mr. Gene Haislip to appear before your Select Committee on August 12, 1982, to present DEA's views on the look-alike problem. Be assured that DEA will continue to work with other Federal agencies, state and local governments and the pharmaceutical industry to develop an effective strategy to eliminate this problem.

Enclosed are DEA's responses to the questions which you submitted. If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

FRANCIS M. MULLEN, Jr.,
Acting Administrator.

Enclosure

1. DEA is not aware of any involvement of organized crime in the look-alike drug business.

2. (a) It is unclear from *U.S.* v. *Gesauldi,* 660 F. 2d 59 (2d Cir., 1981), that the counterfeit drug provision of the Controlled Substances Act (CSA) (21 U.S.C. 843(a)(5)) can be used against look-alike drug manufacturers. The designed intention of 21 U.S.C. 843(a)(5) was to reach manufacturers of counterfeit controlled substances and not look-alikes containing noncontrolled substances. Further, the Gesauldi case involved the possession of counterfeit drug dies capable of producing exact replicas of a controlled product. How the courts would view the use of this statute to prosecute the manufacturers of products which are similar in appearance to, although not exact replicas of, controlled products is unclear.

Although DEA has provided the particulars of the Gesauldi case to interested prosecuting attorneys, I am unaware of any prosecutions involving look-alikes, successful or otherwise, based on this statute.

(b) The Food and Drug Administration has been successful in using the counterfeit provision of the Food, Drug and Cosmetic Act against look-alike manufacturers. This appears to be a more appropriate vehicle to use.

However, should the need arise, DEA is prepared to evaluate the use of this statute (21 U.S.C. 843(a)(5)) as well as other alternatives, on a case-by-case basis, as a means of stopping look-alike manufacturers.

3. The DEA Model Imitation Controlled Substances Act, with some modifications, could be adopted for use at the Federal level. At this time it is unclear that further Federal legislation is needed. The model act was designed for states to use and has been adopted in some form by 31 states. Those states which have had look-alike statutes in effect for some time, e.g., Delaware, have had considerable success in decreasing the availability of look-alikes in their jurisdiction. Enforcement of the look-alike laws and prosecution of violators are as important as enacting legislation and must be enthusiastically pursued. DEA is currently assessing the impact and effectiveness of the various Government initiatives in order to determine what, if any, further measures need to be taken at the Federal level.

(a) The Model Imitation Controlled Substances Act makes it unlawful to manufacture, distribute, possess or advertise imitation controlled substances. An imitation controlled substance is defined as a noncontrolled substance which either looks like or by representations made would lead a reasonable person to believe that the substance is a controlled substance. In the case of look-alike pills which do not resemble controlled drug products, the applicability of the model act would depend on the representations made. Statements made by the owner as to the nature, use of effect of the substance or the resale value of the substance, the manner in which the substance is packaged, evasive actions by the owner to avoid detection by law enforcement authorities, prior convictions of the owner and the proximity to controlled substances are all relevant factors to be considered in determining whether the substance is an imitation controlled substance.

(b) A copy of the model act is enclosed.

4. If DEA were given jurisdiction to enforce a new Federal law prohibiting the manufacture, distribution or possession of look-alikes, there would be a considerable drain on our already limited resources. Approximately 80 additional investigators would be required to effectively enforce new Federal look-alike legislation. Additionally, approximately 10 new U.S. Attorney positions would be required for the prosecution of cases involving look-alikes. The number of additional personnel is depend-

ent on the form of legislation and the degree of difficulty involved in prosecutions under the law.

5. DEA is aware of 31 states which have enacted look-alike laws with an additional 15 states with legislation pending. Most state look-alike laws are composition of DEA's model act, the AMA model status and the Delaware look-alike act.

6. The criminal portion of the Wisconsin statute has been contested in litigation. The outcome of that litigation is unknown at this time. The civil portion of the Wisconsin statute, however, continues to be used. The Alabama statute involving counterfeit and look-alike substances is currently being challenged with a rehearing of the case requested before the Alabama Court of Criminal Appeals.

7. Based on information currently available to DEA, phenylpropanolamine (PPA) does not meet the necessary criteria for scheduling under the CSA. Specific findings for PPA must be made before it can be placed under control. Additionally, a scientific and medical evaluation and scheduling recommendation must be received from the Secretary for Health, Department of Health and Human Services (DHHS), before a scheduling decisions can be made. DHHS has made no such recommendation nor in our opinion does PPA meet the necessary criteria for control at this time. Perhaps, before the control of PPA under the CSA is pursued, some though should be given to making products containing PPA prescription items.

8. (a) DEA's efforts at the local level have been aimed at providing factual information to community and other groups concerning the potential dangers of look-alikes and encouraging citizens to press for new state and local legislation or enforcement of existing legislation dealing with look-alikes.

(b) The adoption of state legislation by 31 states with legislation pending in another 15 states has been due in part to the efforts of local community groups. Los Angeles and cities in Nebraska, Arizona, Michigan and Washington have adopted or proposed local ordinances to combat the look-alike problem.

9. (a) In March/April 1982, DEA's Office of Diversion Control (formerly Office of Compliance and Regulatory Affairs) conducted an informal survey of its field offices to determine the status of the look-alike problem throughout the United States. A copy of that survey is enclosed. Although DEA does not have the resources to devote full-time to monitor the look-alike problem, continuous contacts by DEA's Diversion Investigators, Special Agents, chemists, and intelligence analysts with members of the law enforcement community pharmaceutical industry, forensic community and other groups enable DEA to monitor the look-alike problem.

(b) Personnel in the DEA field offices rely on citizen complaints, information from local law enforcement and forensic personnel, pharmaceutical manufacturers and distributors, state regulatory bodies, local drug abuse treatment officials, and other Government officials to determine the extent of the look-alike problem. Emergency room and medical examiner data are also examined. During 1981, a category for look-alikes was set up in the DAWN system.

10. (a) Intelligence reports estimated that between January and June 1981 approximately 30 million dosage units of look-alikes were produced weekly. Shortly afterward, it was estimated that production decreased to 5 million dosage units per week.

(b) DEA's survey in March 1982 indicated at least 10 look-alike manufacturers in existence. FDA has access to more precise information.

(c) DEA's March 1982 survey indicated that there were at least 200 distributors in business sometime during 1981.

(d) Since look-alikes contain only noncontrolled ingredients, DEA has no registration or reporting requirements for the manufacturers or distributors of these products. Thus, DEA does not have specific data with which to determine the amount of sales or numbers of manufacturers or distributors. However, our March survey indicated that many storefronts and boutiques have closed, that a number of distributors and at least one manufacturer have gone out of business, that certain capsules are in short supply and, in general, 10 states have noted a marked decrease in availability and advertising.

11. (a) DEA is currently looking at the status of the look-alike problem, assessing the impact of Federal, state and industry initiatives and reviewing the options available to us before making any further recommendations to the interagency task force.

(b) The interagency task force is a voluntary, ad hoc group consisting of representatives of DEA, FDA, U.S. Postal Service, IRS, FTC, and recently NIDA. The group has met four times since last October, twice at the principals level (December 10, 1981, and March 1, 1982). The interagency group serves as a medium for exchanging information and discussing the need for and feasibility of new initiatives by each agency. Through this group, DEA has provided ballistics analysis, expert

testimony and visual aids to the FDA and U.S. Postal Service in support of civil actions taken by them. The group was instrumental in the exchange of information which resulted in the actions taken in the Frye case.

(c) No written reports have been produced by the interagency group as yet.

MODEL IMITATION CONTROLLED SUBSTANCES ACT

Section 1. Definitions

a. The term "controlled substance" means a substance as defined in (insert appropriate citation for definition of "controlled substance" in State Controlled Substances Act).

b. The term "distribute" means the actual, constructive, or attempted transfer, delivery, or dispensing to another of an imitation controlled substance.

c. The term "manufacture" means the production, preparation, compounding, processing, encapsulating, tableting, packaging, or repackaging, labeling or relabeling, of an imitation controlled substance.

d. The term "imitation controlled substance" means a substance that is not a controlled substance, which by overall dosage unit appearance (including color, shape, size and markings), or by representations made, would lead a reasonable person to believe that the substance is a controlled substance. Nothing in this Act shall apply to a noncontrolled substance that was initially introduced into commerce prior to the initial introduction into commerce of the controlled substance which it is alleged to imitate. In those rare cases when the appearance of the dosage unit is not reasonably sufficient to establish that the substance is an "imitation controlled substance" (for example in the case of powder or liquid), the court or authority concerned should consider, in addition to all other logically relevant factors, the following factors as related to "representations made" in determining whether the substance is an "imitation controlled substance":

(1) Statements made by an owner or by anyone else in control of the substance concerning the nature of the substance, or its use or effect.

(2) Statements made to the recipient that the substance may be resold at a price substantially higher than the usual and customary price for the substance.

(3) Whether the substance is packaged in a manner normally used for illicit controlled substances.

(4) Evasive tactics or actions utilized by the owner or person in control of the substance to avoid detection by law enforcement authorities.

(5) Prior convictions, if any, of an owner, or anyone in control of the object, under state or Federal law related to controlled substances or fraud.

(6) The proximity of the substances to controlled substances.

Section 2. Offenses

a. Manufacture or distribution.—It is unlawful for any person to manufacture, distribute, or possess with intent to distribute, an imitation controlled substance. Any person who violates this section shall be guilty of a crime and upon conviction may be imprisoned for not more than ——, fined not more than ——, or both.

b. Distribution to a minor.—Any person 18 years of age or over who violates Section 2a by distributing an imitation controlled substance to a person under 18 years of age is guilty of an aggravated crime and upon conviction may be imprisoned for not more than ——, fined not more than —— or both.

c. Possession.—It is unlawful for any person to use, or to possess with intent to use, an imitation controlled substance. Any person who violates this section is guilty of a crime and upon conviction may be imprisoned for not more than ——, fined not more than ——, or both.

d. Advertisement.—It is unlawful for any person to place in any newspaper, magazine, handbill or other publication, or to post or distribute in any public place, any advertisement or solicitation with reasonable knowledge that the purpose of the advertisement or solicitation is to promote the distribution of imitation controlled substances. Any person who violates this section is guilty of a crime and upon conviction may be imprisoned for not more than ——, fined not more than ——, or both.

e. Immunity.—No civil or criminal liability shall be imposed by virtue of this Act on any person registered under the Controlled substances Act who manufacturers, distributes, or possesses an imitation controlled substance for use as a placebo by a registered practitioner in the course of professional practice or research.

Section 3. Forfeiture

(Insert designation of state civil forfeiture section) is amended to provide for the civil forfeiture of imitation controlled substances by adding the following after paragraph (insert designation of last category of forfeitable property):

"( ) all imitation controlled substances as defined by (list appropriate citation for this Act in the state's statutes).

Section 4. Severability

If any provision of this Act or the application of the Act to any person or circumstance is held invalid, the invalidity does not affect the other provisions or applications of the Act which can be given effect without the invalid provision or application and to this end the provisions of this Act are severable.

COMMENT

The Model Imitation Controlled Substances Act incorporates by reference certain definitions in the applicable State Controlled Substances Act, but does not attempt to incorporate or amend the definition of "counterfeit substance" in the State Controlled Substances Act. DEA believes it would unnecessarily confuse the issues to attempt to amend the definition of "counterfeit substance" in the State Controlled Substances Act. Therefore, the Model Act uses a new term of "imitation controlled substance" as the key to the Model Act.

DEA believes that many of the existing and draft State Acts which have sought to reach the look-alike problem have placed too much emphasis on the representations made by the seller of the substances. Hence, the DEA Model Act seeks to place emphasis on the "look-alike" nature of most of the substances involved to sustain the burden of proving a violation. The portion of the DEA Model Act which deals with "representations made" by the seller is not really intended to reach look-alikes in table or capsule form, but rather, is intended to reach those cases where powder or liquid is represented to be controlled substances. Most cases related to powder will involve alleged cocaine or heroin and most cases related to liquid will involve alleged PCP or other hallucinogenic drugs.

The sections of the Model Act which deal with penalties, advertisement, forfeiture, and severability are framed from the pattern used in the Model Drug Paraphernalia Act, drafted by DEA in August 1979. As of October 1981, the Model Paraphernalia Act has been enacted by 23 states and many localities, and has been upheld at the state level by every Federal District Court and Appeals Court that has considered it. As in the Model Paraphernalia Act, the Model Imitation Controlled Substances Act leaves to each state the specific penalty to be inserted as a sanction for each of the criminal offenses proscribed by the Act.

DEA MARCH 1982 LOOK-ALIKE SURVEY RESULTS, MEMORANDUM FROM FRANK SAPIENZA, REGULATORY CONTROL DIVISION, TO GENE R. HAISLIP, DIRECTOR, OFFICE OF COMPLIANCE AND REGULATORY AFFAIRS

In early March, I requested that the Compliance Division (CRC) conduct an informal survey of their field offices to update the status of the look-alike problem throughout the United States. CRC informed me that the survey would be limited to readily retrievable and available information. Responses were received from all states except Arkansas, Hawaii, Mississippi, Nevada and South Carolina. Nine questions were asked with varying amounts of information received from each. Nevertheless, some general statements can be made based on the survey. These are:

(1) The look-alike problem has affected the entire country, some sections more heavily than others.

(2) Cocaine substitutes are now a significant addition to the look-alike problem in many areas.

(3) Most states (44 out of 50) have passed or have pending look-alike legislation.

(4) More states indicated the problem is decreasing than increasing (10 to 3). The states noting a decrease have look-alike legislation or are using pharmacy regulations.

(5) The Federal response (DEA, FDA, U.S. Postal Service) has had an impact. In some cases, it has driven companies out of business and in other cases, it has caused changes in their modus operandi. However, significant core of these businesses appear ready and willing to change and/or fight to remain in business.

(6) Many state officials are not convinced that state legislation is the ultimate answer and are looking to the Federal Government for further assistance.

Following are the specific questions asked and a summary of the responses received. In most cases, not all of the questions were answered by all of the states.

(1) Which states have proposed or enacted look-alike legislation?

As of April 1, 1982, 13 states have enacted specific look-alike legislation. An additional 4 states have been using so-called "Turkey laws." There are look-alike laws pending in another 26 states at this time. Of the 8 states not reporting look-alike legislative action, at least one is considering legislation and one is relying on local ordinances (Montana), and no information was received from Hawaii and Nevada.

(2) What jurisdictions have had prosecutions under these laws? How many? Were they successful? At what level? What were the penalties?

Only 2 states, Connecticut and Delaware, have had successful prosecutions. Delaware's prosecution was against a distributor and resulted in a fine and probation. Kansas has an active distributor case. California and Texas have had successful prosecutions under false advertising, misbranding and/or mislabeling statutes. Michigan has used nuisance laws against retailers. Ohio, Oklahoma, Washington and Wyoming have used Turkey statutes successfully. Colorado and Wisconsin have had arrests but no prosecutions as yet.

(3) Do state or local officials feel that their look-alike laws are working and/or sufficient?

Connecticut and Delaware responded that their laws are working. Louisiana feels theirs has had an impact. Oklahoma and Pennsylvania are optimistic. Many states believe that although it is really too early to tell, the state laws will not be effective or sufficient. District Attorneys in Colorado have refused to prosecute. Wisconsin's and Indiana's laws are being contested. Concern was expressed over the uncertainty of state jurisdiction over distributors who do not distribute in the state in which they are physically located. States are more concerned over interstate shipment into their states than with production within their own boundaries. Consequently, they believe the Federal Government should step in.

(4) How many look-alike manufacturers are in your state? Distributors? Retailers?

Of the 45 states reporting, only Alabama (1), Georgia (1), Illinois (1), Indiana (1), New York (7) and Pennsylvania (1) reported manufacturers. The FDA lists 9 or 10 known look-alike manufacturers. Our survey indicates that there are, at the very least, 200 distributors throughout the country. Most states indicated that distribution was by mail order with many distributors selling only out of state. California and Washington indicated sales through record shops, head shops, convenience stores and health food stores. Arizona, Missouri and New Mexico indicated sales through store fronts, many of which have closed.

(5) Are you aware of a shift by manufacturers/distributors to "look-alikes" not resembling controlled products, e.g. red, white and blue capsules?

California, Ohio, Pennsylvania and Texas indicated a definite trend to individualized products such as purple tablets, football and ovid-shaped tablets containing caffeine, ephedrine and phenylpropanolamine. The other responding states were unaware of such a shift.

(6) Have any local jurisdictions taken additional measures against look-alikes?

Cities and counties in Washington are successfully enforcing Turkey laws against look-alikes. Los Angeles and cities in Nebraska and Kansas are drafting look-alike ordinances similar to the state laws. California cities are pursuing educational campaigns.

(7) How are look-alikes advertised?

Most states reported that the predominant form of advertising involves the mailing or distribution of circulars to young people. Additional advertising methods include newspapers, magazines, billboards, underground publications, CBs, and college publications. A number of states have indicated that much of the advertising has switched from popular magazines and newspapers to underground publications and direct mail solicitations.

(8) In general, has there been any change in the availability and/or use of look-alikes in your locality since mid-1981?

Of the 44 states responding, only West Virginia indicated that there was no look-alike problem in their area. Colorado, Ohio and Wyoming reported definite increases. Ten states, California, Florida, Idaho, Iowa, Kentucky, Maryland, Montana, Oregon, Utah and Washington, reported excellent availability or substantial problems. Seven states, Connecticut, Kansas, Louisiana, Michigan, Minnesota, New Jersey and Pennsylvania, reported slight or moderate decreases in use or availability. Delaware, the first state to enact look-alike legislation, noted a dramatic decrease in availability. Texas and Wisconsin have noted decreased open advertising.

Additionally, 20 states in various sections of the country indicated a problem with cocaine substitutes.

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
NATIONAL INSTITUTE ON DRUG ABUSE,
Rockville, Md., November 16, 1982.

Hon. LEO C. ZEFERETTI,
Chairman, Select Committee on Narcotics Abuse and Control,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Enclosed are the responses to your follow-up questions which resulted from the hearing on look-alike drugs on August 12, 1982.

If I can provide further information, please do not hesitate to call me.

Sincerely yours,

WILLIAM POLLIN, M.D.,
Director.

Enclosure.

FOLLOWUP QUESTIONS TO THE AUGUST 12, 1982 HEARING ON LOOK-ALIKE DRUGS

Question 1. a. In your view, what are the highest priority needs for data about the nature and extent of the look-alike drug problem?

b. Can these needs be met from existing data sources? If not, what steps are being taken to satisfy these needs?

c. Is NIDA's current budget, as well as your requested budget for 1983, sufficient to ensure that the collection and analysis of data needed to more accurately assess and monitor look-alike drug use can be undertaken?

Answer. We are convinced that the highest priority need for data about the nature and extent of the look-alike problem is to separate out the use of "true look-alike" substances from amphetamines and from "over the counter" stimulants. The National Institute on Drug Abuse annual High School Senior Survey for 1982 has been modified to achieve this goal. We are currently exploring our data analysis and epidemiology programs to determine how best to collect, analyze, and accurately monitor the look-alike problem.

Question 2. a. Is NIDA's current budget, as well as your requested budget for 1983, sufficient to ensure that an active program of public information dissemination about look-alikes can be undertaken?

Answer. NIDA's fiscal year 1983 budget is consistent with the President's request. Given the current mandates for fiscal restraint, NIDA's allocation of funds for public information and dissemination of information on look-alikes is adequate.

b. Will you please provide for the hearing record a copy of the NIDA Capsule on look-alike drugs you referred to in your testimony?

(See Attachment A p. 112)

c. Will you please also provide for the hearing record a copy, or summary, of the survey of the Addiction Research Foundation in Canada?

(See Attachment B p. 113)

Question 3. a. What contributions and recommendations do you plan to make to the interagency task force formed to coordinate efforts to combat the look-alike problem?

b. What initiatives have begun and are being planned?

c. Will you please submit for our hearing record a copy of the report by the task force mentioned in your testimony?

Answer. NIDA has been an active participant in the interagency task force formed to coordinate efforts to combat the look-alike problem. In addition, an in-house task force has been created at NIDA to coordinate NIDA activities on look-alikes and to generate new initiatives for NIDA in the look-alike area. Several members of the NIDA task force are also members of the interagency group and serve as a two-way communication focus between these two working groups. Attached is a draft of the NIDA Task Force on "Look-Alike/Amphetamine Plan," which is a comprehensive listing of research, prevention, and technology transfer initiatives. (See Attachment C p. 114)

Question 4. Does NIDA have plans to initiate new, or reformulate old, surveys so as to determine the overlap of usage of various drugs measured in the NIDA survey, Student Drug Use in America, 1975–1981? Can you now determine whether the same groups of students account for a major proportion of all of the use of various drugs (and alcohol), or whether the abuse is spread throughout the student population?

Answer. As mentioned above, NIDA has reformulated the High School Senior Survey to include specific questions to determine actual use of look-alike substances. The National Household Survey makes use of photo-cards from which individuals literally point to the pictures of drugs they have used. This technique does not lend itself well to identifying "look-alikes;" however, alternate methods are being explored for use in the national household survey.

Currently survey data allow for the determination of how drug abuse is spread across the standard population. For example, in the class of 1981, 52 percent report use of marijuana and 34 percent of that group report use of other drugs.

NIDA is continuously updating and reformulating its existing surveys, and exploring the initiation of new studies to better track and predict the drug-taking behaviors of the American public.

[Attachment A]

Look-Alike Drugs

Two categories of drug products contribute to the look-alike drug problem: true look-alikes and over-the-counter (OTC) stimulants and depressants.

True look-alike drugs are products that mimic prescription stimulates and depressants (in size, color, shape, or markings) such as amphetamines, methaqualone (Quaaludes), or cocaine. Those look-alikes promoted as "uppers" for their amphetamine-like properties generally contain one or more of the following nonprescription stimulants: caffeine, phenylpropanalomine (PPA), or ephedrine. Look-alike products marketed as tranquilizers or "downers" usually contain only antihistamines.

The look-alike drug problem also involves OTC stimulants and depressants which do not require prescriptions because they are not registered under the Controlled Substances Act. Most of these psychoactive substances are marketed as diet aids, "pep" pills, or sleep aids. They are not manufactured to deceive the public, and do not look like controlled substances. However, these products contain the same ingredients (PPA, caffeine) in various combinations as do the true look-alikes.

DISTRIBUTION

Manufacturers of look-alike drugs promote the products through college newspapers, handbills at truckstops, unsolicited literature from mail-order firms, or through storefront operations often located near high schools or college campuses. Distributors promote the drugs as "100 percent legal" or "legal stimulants" and have even offered free samples through the mail. In some cases, the products are advertised by the street names for amphetamines and barbiturates (e.g., Black Beauties, Yellow Jackets, Speed, and White Crosses), and because of their physical appearance, the buyer may be led to believe that he or she is purchasing a controlled substance.

DANGERS OF LOOK-ALIKES

A principal concern regarding the health effects of look-alikes and other OTC stimulants and depressants is the developmental danger they pose for young people. For maturing adolescents, easy availability of legal highs increases the likelihood of developing a pattern of use of drugs as a shortcut to pleasure and as a substitute for satisfaction derived for realistic achievement.

In terms of physical effects, several well-documented reports show severe hypertension and cerebral hemorrhages resulting in death associated with the abuse of the ingredients in look-alike drugs. Central nervous system and circulatory system reactions to caffeine include insomnia, restlessness, and exitement, as well as hypertension and tachycardia. The administration of ephedrine may cause reactions similar to those experienced from amphetamine use including anxiety, restlessness, weakness, throbbing headache, respiratory difficulty, and palpitations. Potentially life-threatening effects are hypertension and cardiac arrhythmias. The toxic effects of PPA are similar to those of ephedrine.

Individuals who have been purchasing look-alikes on the "street" may unknowingly obtain real amphetamines and take quantities sufficient to result in overdose. Conversely, individuals who have been abusing amphetamies may underestimate the potency of look-alike drugs, and take an excessive quantity, seeking the expected "kick," with a resultant toxic reaction.

The Food and Drug Administration has confirmed 12 deaths due to look-alike drugs, primarily associated with caffeine overdose. Ten of the 12 deaths occurred in females, nine of them less than 30 years old. These look-alike drug overdose cases can easily be misidentified by emergency room personnel. A review of the 12 look-

alike drug deaths indicates that in seven of the cases the drug involved was originally thought to be a stimulant other than a look-alike.

DAWN DATA

The National Institute on Drug Abuse recently added a look-alike drug category to the Drug Abuse Warning Network (DAWN) reporting system. However, reports are still too few for meaningful analysis. In the past, look-alikes may have been recorded in the hospitals and emergency rooms, that comprise the DAWN system as amphetamine, or if known to be look-alikes, as separate mentions for caffeine, ephedrine, and PPA. Emergency room mentions of PPA and caffeine increased steadily from 1977 to 1980. Ephedrine mentions have been relatively stable, with the exception of a sharp, unexplained downturn in 1979.

DAWN emergency room visits and medical examiner reports for amphetamines during the period 1978 to 1980 increased dramatically: emergency room mentions by approximately 80 percent and medical examiner mentions by 40 percent. One factor possibly contributing to this difference in the rate of increase is that medical examiner reports are usually verified by toxicological examination, while emergency room reports usually are not. The self-reported use of amphetamines, which include over-the-counter diet aids, may also include look-alikes. If this is true, then the use of these products may result in more health-related emergencies than is currently realized.

STATE LEGISLATIONS AGAINST LOOK-ALIKES

During the past year, 33 State legislatures considered more than 100 bills regarding the look-alike drug problem. As of September 1982, 35 States have passed legislation banning the distribution of look-alike drugs.

[Attachment B]

S. 310—Substudy No. 1203, Preliminary Report of Alcohol and Other Drug Use Among Ontario Students in 1981, and Changes Since 1977 and 1979

(By Reginald G. Smart, Michael S. Goodstadt, Margaret A. Sheppard, Godwin C. Chan, Edward M. Adlaf, and Carolyn B. Liban)

Summary and Discussion

This report should be viewed as preliminary, to be supplemented by later reports on other aspects of the data. The principal results of the 1981 study include the following:

1. Alcohol, tobacco and cannabis were the most popular drugs in 1981, as measured by the proportion of students who reported having used the drug in the previous 12 months; 75, 30 and 30 percent of students, respectively, reported using these drugs in the previous year. All other drugs were used by much smaller proportion (i.e. 12 percent or less) of students.
2. As measured by the frequency of drug use among all students, the most commonly used drug was tobacco (used daily by 22 percent of all students) followed by cannabis (approximately 3 percent had used it 20 or more times in the previous month), and alcohol (1.4 percent had used it on an average of four or more times a week during the previous 12 months).
3. As measured by the frequency of drug use among those who reported having used a drug, the most popular drug was, again, tobacco, followed by cannabis and alcohol: 72 percent of smokers smoked every day; 10 percent of cannabis users used it 20 or more times in the previous month; 2 percent of drinkers drank, on average, 4 or more times a week.
4. The frequency of use of all drugs except alcohol, tobacco and cannabis, was relatively rare, even among drug users.
5. More males than females used cannabis, prescription barbiturates, heroin and cocaine; females continued to use tobacco more than male students.
6. Younger students (those 13 years and less, or in grade 7) were much less likely than older students to use any drugs, except for glue and other solvents.
7. Older students (18 years and older, or grade 13) were less likely than their immediate juniors (16–17 year olds, or grade 11) to use any of the drugs, except for alcohol, which they were more likely to use.
8. The Western region of Ontario consistently showed a higher proportion of drug users, especially when compared to the Metropolitan Toronto region, which exhibited the lowest prevalence of drug use.

(9) Comparisons between 1981 results and previous survey years, 1977 and 1979, require caution, due to differences in sampling characteristics. The 1981 results compared to 1979, however, showed a significant decline in the proportion of male tobacco and alcohol users, no continuation of females' previous increase in tobacco use, and no further increase in cannabis use for either sex. The 1981 data also showed significant overall reductions in the use of solvents other than glue. No drugs showed a significant increase in the proportion of users between 1979 and 1981.

(10) Comparisons between 1981 and 1977 suggested few changes in the prevalance of drug use between these years. The proportion of alcohol users has continued to remain stable between survey years; cannabis, in spite of slight declines in use since 1979, is still used by a larger proportion of students than in 1977. Non-prescription stimulant use appeared to increase among females between 1977 and 1981.

Many of the results found are similar to those found in the previous surveys. Alcohol, tobacco and cannabis are still the most popular drugs. Most types of drugs, except for glue and other solvents, are more popular among older students (except grade 13). Also illicit drug use, except for cannabis, is still relatively infrequent among users.

The 1981 survey indicated very few differences between males and females in drug use. In 1979 males showed greater use of nine drugs than females. However, by 1981 a greater proportion of make use was found for only four drugs (cannabis, prescription barbiturates, heroin and cocaine). We note, too, that males significantly decreased their use of two drugs (alcohol and tobacco) while females did not significantly decrease their use of any drug.

Some interesting and novel results, however, were suggested. There are no drugs for which overall use increased since 1979. This is most unusual, as past surveys in Ontario and in Metropolitan Toronto since 1968 have shown consistent increases in the use of cannabis and, in earlier years, alcohol use. In fact, the increase in cannabis use between 1977 and 1979 was substantial (from 25.1 to 31.7 percent). The results of the present survey may have been due to either: (i) changes in the sampling procedures employed in 1981; or (ii) some stabilization taking place in the use of cannabis and the other drugs which had shown an increase in 1979. Studies conducted among high school seniors in the United States (Johnston et al., 1979) have also shown some stabilization in the use of cannabis. Whether this is due to improved education about adverse effects of cannabis, economic factors, or more general socio-cultural changes, cannot be determined at this time. In any case, it appears that drug use in 1981 was more similar to 1977 and that at least for some kinds of use (e.g. cannabis and tobacco), 1979 may have been an unusual or a peak year; whether it will remain so will be the focus of later surveys.

[Attachment C]

In the latter half of 1981, the National Institute on Drug Abuse, through its work with a number of interagency groups and based on preliminary results from a National High School Survey, became concerned about the rise in reported stimulant abuse and especially reports of the increasing availability and of the abuse of the so-called "look-alike" or counterfeit stimulants.

Reports from various sources noted especially this rise among youth. The Institute then established a work group which developed the following comprehensive plan to coordinate our response to this problem and to provide a model which would more quickly identify new and emerging patterns of substance abuse.

NIDA Look-Alike/Amphetamine Plan

OBJECTIVES

1. To develop comprehensive information on the nature and extent of the look alike (also non-look-alikes, OTC stimulants) and amphetamine abuse phenomena. Identify strengths and weaknesses of existing data collection efforts and develop approaches which will address gaps in the knowledge base.

2. To continue to develop and update research knowledge on all component drugs in this group, identifying appropriate action steps to transfer information, and to provide prevention and treatment strategies to address problems associated with these drugs.

3. To provide a framework to coordinate the identification of new patterns of abuse involving these substances and develop plans for technology transfer and knowledge dissemination activities to a variety of target audiences in both the public and private sector, with emphasis on development of prevention and treatment approaches.

NATIONAL INSTITUTE ON DRUG ABUSE LOOK ALIKE AND AMPHETAMINE PLAN

Activity	Timing	Comment
I. Definition of the problem and knowledge development		
A. Review existing data sources to assess their ability to provide necessary data elements and identify gaps in existing data collection efforts.	Next 60 days	Ongoing.
1. Continue to monitor mentions of caffeine, and PAA containing products, including OTC diet aids.		Do.
2. Include article in next DAWN Reporter alerting reporting units to look alike problem.	Completed	Article appeared in DAWN Report alerting reporting units to increase awareness and reporting of the look alike problem
3. Determine feasibility of joint project between DDID and the DR on urine sample analysis at the University of Utah for "look alikes" obtained from emergency rooms. (Submit report).	Next 60 days	
4. Evaluate utility of "Drug Buy Analysis Data" obtained from DEA in defining the prevalence of look alikes and amphetamines. (Submit report).	Next 30 days	
5. Review household survey for data on look alikes. (Submit report).	do	
6. Continue to collaborate with FDA, DEA, U.S. Postal Service, and the FTC on information exchange activities.		Ongoing.
B. Develop comprehensive data collection method for look alikes and other emerging drugs of abuse.	Next 120 days	Could involve use of selected SMSA in which NIDA could provide police "buy" information, treatment admission data and data from correctional service agencies.
1. Convene meeting and review proposed approaches		
2. Develop proposed approach for data collection method	Next 120 days	
3. Incorporate ICDC recommendations on potential new drugs of abuse.		The ICDC has been reliable in providing information on emerging drugs of abuse
C. Data collection method implemented	January 1983	
D. Continue to alert ICDC to task force efforts and interests on activities involving emerging drugs of abuse and solicit their review and comment on activities related to data gathering and information development.	Next 30 days	
II. Technology transfer and information dissemination initiatives		
A. Prepare NIDA capsule on look alikes		Completed and reviewed by Task Force on look alike drugs.
1. Distribute to appropriate agencies in the public and private sector with interest in substance abuse.		
B. Prepare an issue of the DCA clinical notes addressing health consequences of look alikes.	Next 60 days	
1. Distribute to States, professional associations, treatment programs, hospital emergency rooms, medical examiners, and mental health centers, etc.		
C. Develop and distribute a look alike fact sheet to the SSA's, etc.	Completed	
D. NIDA review and comment on DEA information pamphlet and look alikes.	do	
E. Develop and Distribute NIDA capsule on amphetamines	do	In final clearance.
F. Collaborate with the National Association of Concerned Parents, encourage and solicit their assistance in distributing information such as NIDA capsules to local groups, schools, PTA's etc.		Ongoing.

NATIONAL INSTITUTE ON DRUG ABUSE LOOK ALIKE AND AMPHETAMINE PLAN—Continued

Activity	Timing	Comment
G. Establish panels at workshops and professional associations, etc..	October 1982	Emphasis on overall information and public awareness campaign should be directed toward all stimulant use. There is a continued need for additional data on nature and extent of the problem, health consequences of abuse, etc
1. Suggested topic: Comprehensive approach for all stimulant abuse.		
a. Lloyd Johnston could discuss implications of high school survey.		
b. Edgar Adams to describe DAWN, pharm chem data, etc.		
2. Planning for ADPA conference to be held from August 29 to September 1, 1982.	Next 120 days.	
3. Present information on look alikes at June NASADAD meeting.		Completed.
4. Present panel on substance abuse and youth (including look alikes) at the American Academy of Child Psychiatry.	October 1982	
H. Pamphlet at stimulants	Next 120 days.	This format conveys NIDA's concern about stimulant abuse in the population and the dangers of dependence.
1. Develop combined information on amphetamines, look alikes, counterfeits, and OTC's in a single pamphlet.		
2. Develop feature articles on this topic for publication in journals, newsletters, magazines, newspapers, etc.		
I. Continue advertising council project designed to publicize the health consequences of drug use. 1. Presentation of prevention messages that focus on health promotion, "Saying no" strategies, etc.		
J. Conduct special ethnographic studies	Next 30 days	Could use NIDA supported local epidemiology network to assess user characteristics, patterns of us, how drugs are obtained and motivation for use, etc.
1. Determine feasibility and estimated cost (Submit report.).		
2. Initiate study. (Submit progress reports.)	Next 120 days	
K. Further epidemiologic study will seek to determine	Next 90 days	Efforts should be part of the Institute's epidemiology plan.
1. Adverse effects on personality of chronic users, health consequences, etc.		
2. Evaluate reported psychotic episodes to determine relationship between the drug and the users personality; determine if certain users are prone to such reactions.		
3. Determine adverse affects of the Look alikes on intellectual functioning and psychosocial development, especially in the adolescent and younger individual.		
4. Determine whether the look alikes (also non look alike-pseudospeed)/amphetamines reflects a new abuse problem or is part of a polydrug abuse phenomena where this group of substances is used as a fad, and/or because of their easy availability.		

NATIONAL INSTITUTE ON DRUG ABUSE LOOK ALIKE AND AMPHETAMINE PLAN—Continued

Activity	Timing	Comment
L. Review of existing research is needed to identify grants and contracts which deal with the look alike/amphetamines and determine; (a) the feasibility of conducting research (preclinical and clinical) studies.	Next 180 days	The primary purpose is to provide a basis for long term study of these substances, including a mechanism to make it possible to initiate approaches, to other emerging drugs of abuse. A workable system can be established as part of the Institute's technology transfer capabiiities.
1. Receive status report from DR identifying current research capable of developing information about the look alikes.		
2. Determine feasibility of conducting a multidisciplinary technical review on the look alikes/amphetamines to consider implications for further research. This could produce a monograph providing a survey of relevant on-going studies. The technical review may include biological, neurochemical and preclinical behavioral aspects as well as ethnographic and epidemiologic issues for further study and investigation. It may also discuss consequences of abuse including overdose and other toxicity issues, modes of abuse, and treatment and medical/clinical management of look alike/amphetamine abusers.		
a. Determine feasibility for technical review. (Submit report.)	Next 30 days	Recommendation for a technical review has been forwarded to DR.
b. Develop proposal for technical review including possible attendees.	Next 180 days	
M. Preclinical research studies	Current data shows that PPA and caffeine have no reinforcing potential in baboons. Ephedrin has mild reinforcing potential. Little is known about these drugs in combination, yet since this is the usual form in which these drugs are consumed it is vital to understand the additive effects, if any.	
1. Assessment of abuse potential of PPA, ephedrine, and caffeine.		
a. Studies of self-administration behavior of look alike products in primates are planned.		
2. Pharmacokinetic studies of look alikes		
3. Tolerance and dependence producing effects		
N. Clinical research		
1. Analysis of biological and/or pill samples from emergency room patients reporting amphetamine and/or look alike adverse reactions.	Next 180 days	
2. Behavioral toxicity of look alikes		
3. Effects of look alikes on performance		
4. Studies of patterns of use of look alikes especially in the young user.		
III. Training		
A. Conduct a needs assessment to determine training needs of the field. The following mechanisms may be utilized.	Next 120 days	The primary purpose is to assess available materials and their relevancy to identified training needs.

NATIONAL INSTITUTE ON DRUG ABUSE LOOK ALIKE AND AMPHETAMINE PLAN—Continued

Activity	Timing	Comment
1. Health professions task force		
2. The career teachers in drugs and alcohol		
3. The Association for Medical Evaluation and Research in Substance Abuse.		
4. The National Board of Medical Examiners—NIDA Task Force.		
5. The AMA		
6. Medical specialty boards. (Submit report to look alike/amphetamine Task Force with recommendations for follow-up actions).		
B. Clinical, research, and prevention materials on look alikes/ stimulants, and OTC drugs that are developed are distributed to the States, professional groups and organizations, etc.		
IV. Prevention		
A. Alert the public and professional community to the problem of look alikes/amphetamines using best available information.		Effective prevention strategies to discourage use of look alikes are needed, although insufficent information may still exist. Nevertheless, the initial approach will consist of the public awareness/ information efforts outlined previously.
1. Prevention/Education efforts with emphasis on health promotion.		
2. Include look alikes/amphetamines issue in remaining regional family workshops which involve representatives of parents groups, SSA's and prevention professionals.		
3. Distribution of information and discussion with National Federation of Parents.		
4. Prevention strategies should focus on youth, parents, families and emphasize "saying no" strategy, positive peer intervention techniques.		
5. Prevention strategies should also focus on impact of drug on performance, (e.g., driving, learning, job performance in the workplace.		

FEDERAL TRADE COMMISSION,
BUREAU OF CONSUMER PROTECTION,
Washington, D.C., November 22, 1982.

Hon. LEO C. ZEFERETTI,
Chairman, Select Committee on Narcotics Abuse and Control,
U.S. House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: I want to thank you again for the opportunity to testify before the Select Committee concerning look-alike drugs on August 12, 1982. I believe that the hearings addressed in great detail what appears to be a serious national problem.

By letter dated September 1, 1982, you asked me a series of follow-up questions so that the hearing record would be complete. I have now had an opportunity to study those questions, and my answers follow:

Questions 1 (a) and (b). It is our understanding that the FTC staff recommendation for a full investigation of the look-alike industry has been pending in the Bureau of Consumer Protection for over five months.

a. When will the Bureau complete its review of the staff recommendation?

b. What steps are being taken to expedite the Bureau's review of this recommendation?

Answer. As you know, the staff has conducted a preliminary investigation and has requested an expansion to full investigational status. The staff's request has been circulated to the Bureau of Consumer Protection's Evaluation Committee,

which consists of representatives of that Bureau, the Bureau of Economics and the General Counsel's office. The Evaluation Committee has committed itself to complete a review within 30 days. At that time, the Committee will make a recommendation to the Bureau Director, who will then decide whether or not to grant the staff's request for a full investigation.

Question 1(c). When will the Commission act on the staff recommendation?

Answer. The Bureau Director has the authority to act on the staff's recommendation for a full investigation. Commission action will be necessary only in the event that compulsory process is required. The staff cannot predict when the Commission will act on any such staff recommendation.

Question 1(d). How can the FTC properly evaluate what its role should be in solving the problems created by look-alike drugs unless it authorizes a full investigation of the look-alike industry as recommended by staff?

Answer. The Commission staff has conducted a preliminary investigation involving look-alike drugs, which has involved gathering information from public sources and conducting a legal analysis of the facts as we understand them. The information developed during the preliminary investigation is sufficient to permit us to determine whether a full investigation is warranted. Based on the preliminary investigation, the staff has recommended that a full investigation be authorized, so that additional resources can be committed.

[Note: In November 1982, the committee was advised that a full-phase investigation of the look-alike industry had been authorized to study the issue of whether the FTC has jurisdiction in this area, and if so, whether FTC can impose an effective remedy.]

Questions 2 (a) and (b). Your written testimony submitted to the Committee expresses the view that look-alike drug abuse is not primarily an advertising or marketing problem: "The fundamental problem with look-alikes . . . is that they are available at all." You also state, "A product ban may be the only meaningful remedy, and it is unclear whether the Commission's authority provides for such relief."

a. Isn't the FTC's unfairness jurisdiction broad enough to prohibit the manufacture, as well as the marketing of look-alike drugs?

b. Hasn't the FTC used its unfairness authority in the past to ban the production of certain products? Please mention the products, and under what circumstances they were banned.

Answer. I am not aware of any occasion on which the Commission has banned the manufacture of products. However, the Commission has exercised its authority to band the sale of products, but it has done so very rarely. Specifically, our research indicates that the Commission has exercised such authority when it prohibited the sale of gambling devices that (1) would appeal only to children and (2) were marketed only for the purpose of encouraging children to gamble.

Look-alike drugs, however, present a more complicated problem because many ingredients used in look-alikes (or in substitutes for them) may be legally sold over-the-counter if they are appropriately labeled. In such a situation, the Commission's authority to restrict the sale of a product is unclear, although I believe the total prohibition of a product which can be legally sold exceeds the FTC's authority.

Question 2(c). You mentioned that in order for FTC's unfairness authority to be invoked, or considered, three criteria must be met. Please explain the criteria and why their definitions may be undergoing some changes. Further, how and why could this bear on jurisdiction over look-alike drugs?

Answer. At the request of Congress, the Commission in 1980 set forth its general views concerning its "unfairness" jurisdiction. The Commission reiterated those views in a March 5, 1982, letter to the Senate Committee on Commerce, Science and Transportation. I am attaching a copy of that letter for your information.

On both occasions, the Commission stated that a violation of its "unfairness" authority exists if (1) there is substantial injury, (2) consumers could not reasonably avoid the harm, and (3) the injury is not offset by other benefits. Furthermore, legislation adopting those same general principles has been approved by both the House Committee on Energy and Commerce and the Senate Committee on Commerce.

Question 3(a). Look-alike drug have caused the deaths of at least 12 persons, and are responsible for numerous other injuries and adverse reactions. Do these deaths and injuries constitute sufficient evidence of substantial harm from look-alike drugs?

Answer. To determine whether there is "substantial harm," the Commission must look in each case to all the circumstances surrounding a marketing practice. For example, it might make a difference if the adverse reaction you mention occurred at a rate of one in a 100 million persons and not one in a thousand. On the other hand,

it may be that a marketing practice poses such a serious threat of substantial harm that the Commission should act even if no deaths or injuries had occurred.

Question 3(b). What are the benefits to consumers of look-alike drugs that may offset this harm?

Answer. None that I am aware of.

Question 3(c). Since marketing of look-alike drugs is aimed primarily at school-age children, is it appropriate to conclude that these consumers reasonably can avoid the harms that look-alikes cause?

Answer. If, following our investigation, it appears that the marketing of look-alike drugs is aimed at junior high or elementary school age children, I would be of the view that their general lack of judgment and susceptibility to peer pressure would make them considerably less capable of avoiding harm of this sort than adults, college students or perhaps some older high-schoolers.

Question 4(a). Your testimony states, "To the extent that there is advertising (for look-alike products), it often focuses on the mood-altering characteristics of these drugs—claims that are probably not deceptive."

A. Is the truth or falsity of such claims the sole criterion for FTC action against such advertisements?

Answer. No. As I indicated in my testimony, unfairness is also a criterion.

Question 4(b). Are these claims, even if true, and the products they promote consistent with Federal law and policy that discourages the use of drugs for recreational mood-alteration?

Answer. No. However, as I indicated in my answers to these questions and in my testimony, the FTC is under certain constraints which render it unable to reach all violations of federal or public policy.

Furthermore, as I have also indicated, the advertising claims for look-alike drugs are only a small part of the problem. The real problem is that the drugs are available to young people.

Question 4(c). Are you aware of any over-the-counter drug products that are approved by the Food and Drug Administration for the purpose of recreational mood-alteration?

Answer. No. I am not aware of any such products.

Question 5(a). An interagency task force has been set up so that agency efforts to combat the look-alike problem may be coordinated.

a. What actions is the task force proposing to develop a comprehensive strategy for dealing with the look-alike problem at a Federal level?

Answer. To date the value of the task force has been primarily the sharing of information among the participants. To the extent agency participants initiate activities and other participants see no legal difficulties, the task force encourages and supports such initiatives. Each agency participant is committed to a shared goal of finding a solution to what appears to be a widespread problem among young people.

Question 5(b). What contributions and recommendations does the FTC plan to make to the task force?

Answer. The FTC staff will continue to share information with the task force and make recommendations for additional federal activities. In addition, we intend to review any antitrust concerns that may be raised by Warner Lambert's proposal.

Question 5(c). Will you submit for our hearing record a copy of any report, recommendations or summary of any procedings by the task force to date?

Answer. At this time, we are not aware of any recommendations or summaries of task force proceedings.

I hope these responses will be helpful to you and the other members of the Select Committee. Please do not hesitate to contact me if you have additional questions.

Sincerely,

AMANDA B. PEDERSEN,
Deputy Director.

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., November 30, 1982.

Hon. LEO C. ZEFERETTI,
Chairman, Select Committee on Narcotics Abuse and Control,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter transmits our response to your letter of September 1, 1982, in which you address a number of questions to be made part of the record for the hearing on August 12, 1982, concerning look-alike drugs.

We apologize for the amount of time it has taken us to complete these questions. If we can be of further assistance, please let us know.

Sincerely yours,

JOSEPH P. HILE,
Associate Commissioner,
for Regulatory Affairs.

Enclosure.

FOLLOWUP QUESTIONS AND ANSWERS TO OTC LOOK-ALIKE DRUG HEARING

Question 1a. What actions has FDA taken against manufacturers and distributors of the triple combination drugs—PPA, ephedrine and caffeine—that FDA recently decided were unapproved new drugs?

Question 1b. What additional actions are you planning to take in this area?

Answer. FDA originally issued regulatory letters to 14 manufacturers of triple-combination products informing them that these products are unapproved new drugs and that their continued shipment in interstate commerce is a violation of the law. Since your hearing in August, the Agency identified two additional manufacturers and sent regulatory letters to them for a total of 16 firms.

FDA has begun to broaden the scope of its action under the new drug authority to encompass all known, past and present repackers, relabelers and distributors of the triple-combination product. Regulatory letters have been issued to approximately 300 such firms informing them of the new drug status of the triple combination and requesting that they immediately stop distribution. The Agency has already initiated seizure actions against six distributors of triple combination drug products and one distributor of a non-triple combination OTC look-alike based on counterfeit charges.

FDA will follow-up with each distributor, repacker and relabeler to determine if it is honoring commitments made in response to a regulatory letter. The Agency will reinspect to determine whether distribution of triple combination drug products have ceased. FDA is prepared to initiate actions against those firms that do not respond and those who refuse to discontinue distribution of triple combination products. The remedy may include seizure, injunction and/or criminal prosecution.

Question 1c. How, and to what extent, will you monitor the activities of the manufacturers of the triple combination drugs?

Answer 1c. In response to our regulatory letters to the manufacturers, 14 out of the 16 firms stated that they would cease manufacturing and distributing triple-combination products. Reinspection of these firms confirmed their cessation of these activities. Two firms failed to cease distribution of the triple-combination product after receipt of our regulatory letter and seizures of goods have already occurred at these firms. The reinspection also revealed the presence of counterfeit drugs at one firm. The Agency immediately requested and received State assistance in embargoing these drugs, and thereafter seized both the drugs and the equipment used to make them. These seizures netted over 1,000,000 finished capsules and tablets as well as machinery used in the manufacture of the counterfeit drugs valued at more than $100,000.

One of the manufacturers apparently is attempting to curcumvent the new drug determination of the triple combination by substituting theophylline in place of ephedrine. Since both of these ingredients are bronchodilators, FDA regards the theophylline-substituted product as a new drug and has initiated a seizure action against it.

Question 2. When will FDA determine whether to bring criminal charges against the nine look-alike manufacturers who were the subjects of the September 1981 seizures?

Answer 2. FDA is actively considering all the evidence for each of the original nine firms as well as for the additional firms which have been identified since that

time. We expect to reach decisions on each of these firms within the next several months.

Question 3a. As a result of your investigation of look-alike distributors, have you brought imitation drug charges against any of these distributors? If not, do you anticipate bringing such charges? When, and against how many distributors?

Answer 3a. Imitation drug charges have not been brought against any of the distributors. We are relying for now on the unapproved new drug charge in connection with the triple combination of ingredients.

The imitation drug section of the statute has no legislative history or cases interpreting it. In our view, evidence that the imitation product was made or distributed for the purpose of being misrepresented as a controlled substance would be necessary before such a charge was made.

FDA investigators have been instructed to obtain evidence of illicit marketing whenever possible. In fact, information uncovered during investigations of distributors led the Agency to conclude that imitation charges could be brought against several firms. All but one of the firms went out of business, however, before action under the imitation authority could be taken. It was then decided to include the remaining firm in the new drug action, which does not require evidence of misrepresentation. The imitation authority will be used in the future in cases where the necessary evidence has been obtained and an alternative authority is not available.

Question 3b. As a result of your investigation, have you brought counterfeit drug charges against any distributors? If not, do you intend to bring such charges? When, and against how many distributors?

Answer 3b. FDA brought counterfeit charges against one distributor of OTC look-alike drugs where the products did not contain the triple combination. The Agency will continue to take this action whenever it encounters counterfeits which do not contain the triple combination.

Question 3c. What plans does FDA have to use its imitation drug authority against look-alike manufacturers?

Answer 3c. FDA has no present plan to use its imitation drug authority against a manufacturer. The unapproved new drug authority will remain the principal authority as long as it is effective.

Question 4. In his testimony, Mr. Hile mentioned ongoing litigation raises legal questions about the counterfeit authority. What questions are involved that may be relevant to the issue of look-alike drugs?

Answer 4. The "counterfeit" definition in the statute, 21 U.S.C. 321 (g)(2), applies most clearly when a drug manufacturer intends to pass off its product as the product of another manufacturer and, for that reason, copies that product as much as possible and sells the copy as the original. The statutory definition states that a drug is counterfeit if the drug (or its container or labeling) bear the "trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof" of another manufacturer, distributor, etc.

There are two legal questions involving this authority. First, the Government takes the position that, when the statutory likeness has been shown, the drug "thereby falsely purports or is represented to be the product of" another and the total statutory definition has been satisfied. Certain manufacturers have taken the position, on the other hand, that the Government must prove both that a drug bears the trademark, etc. of another and that the drug "falsely purports or is represented to be" the product it copies. No court has yet ruled on that issue.

Second, many look-alike drugs contain markings or other characteristics which are similar to those of the drugs that they are copying, but are purposely not identical. One manufacturer has argued that such products do not meet the statutory definition because they do not have the exact trademark, etc. of any controlled substance and that, in any case, the products neither falsely purport nor are represented to be controlled substances. The Government, on the other hand, believes that the counterfeit definition properly encompasses look-alike products which are not completely identical to the controlled substance they are copying. The manufacturer has contended, however, that the counterfeit provision applies only in situations in which the manufacturer of the copy has attempted to duplicate the appearance of the original drug as closely as possible in order to facilitate passing the copy off as the original, and that whenever the manufacturer of the copy has purposely deviated from the original in some way, the counterfeit provisions do not apply.

This argument was raised in pleadings but apparently will not be litigated in the case referenced above due to an agreement by the manufacturer not to contest the destruction of seized drugs. Consequently, the issue has yet to be decided by the courts as of November 24, 1982, but may be raised in another case in the near future.

Question 5. Should FDA be given injunctive authority over look-alike drugs similar to that which is now available with respect to imitation drugs?

Answer 5. This idea is being considered by the Administration. We will inform you as soon as a position on it is adopted.

(On December 2, 1982, FDA informally advised the Committee that the Department of Health and Human Services would support legislation to enable FDA to obtain injunctions against making and selling counterfeit drugs and related activities which are prohibited by section 301(i) of the Federal Food, Drug, and Cosmetic Act.)

Question 6a. When does FDA expect to complete its consideration of whether phenylpropanolamine (PPA) meet the criteria for scheduling under the Controlled Substances Act? In your judgment, what schedule is appropriate for PPA?

Answer 6a. We are unable to provide you with a timeframe for completing our consideration of phenylpropanolamine because a considerable amount of data is lacking. As you know, under the Controlled Substances Act (CSA), the Attorney General is responsible for placing a drug in a control schedule after gathering the necessary data and requesting from the Secretary of HHS a scientific and medical evaluation and a recommendation on scheduling. In order to make the recommendation, the Secretary must consider three findings in section 202(b) of the CAS which are needed to place a drug in a particular schedule. In making these findings, the Secretary must also consider eight factors in sectio 201(c) of the CSA. A sampling of these factors and a discussion of the difficulties they raise follows.

The first factor, actual or relative potential for abuse, contains the following elements (as provided in House Report 91-1444 Part 1, part of the legislative history of the CSA):

(a) Evidence that individuals are taking the drug in amounts sufficient to create a hazard to their health or to the safety of others.

Three of the deaths attributed to OTC look-alike drugs may have been caused by phenylpropanolamine, but causation has not been proved. Most deaths and medical emergencies attributable to OTC look-alike drugs appear to be associated with caffeine. It is questionable whether the data that have been accumulated to date is adequate to support scheduling. Phenylpropanolamine appears in many OTC and prescription drug products. It is extremely difficult to implicate as the cause of an adverse reaction or death because most cases are not associated with phenylpropanolamine alone, but usually with other drugs in combination. FDA will continue to monitor reports of adverse effects and compile data as they become available through adverse reaction reporting systems. The Agency is using these data as the basis for a study of the risks associated with phenylpropanolamine. The study has been ongoing for sometime, but we do not expect it to be completed until late 1983, because of the small number of adverse effects reported and the difficulty of determining whether reactions are phenylpropanolamine-related or due to other causes.

(b) There is significant diversion of the drug from legitimate channels.

This element should be provable from existing data.

(c) Individuals are taking the drug on their own initiative rather than on the basis of medical advice.

It would be difficult to establish that abusers of OTC look-alike drugs are knowingly seeking out phenylpropanolamine rather than controlled substances or what they know only as "legal stimulants," many of which fortuitously contain phenylpropanolamine. If phenylpropanolamine were removed from these products, it is possible that the market for them would not be affected.

Circumstantial evidence that abusers are at least unwittingly seeking out phenylpropanolamine could be obtained through animal "reinforcement" studies which analyze the attractiveness and/or dependency-forming capacity of the drug. FDA is in the process of initiating such a study, which will either be conducted "in-house" by FDA's National Center for Toxicological Research or by an outside organization.

(d) The drug is so related in its action to a drug already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse.

In this case, it would be necessary to determine whether PPA produces dependency and withdrawal symptoms which are similar to those caused by amphetamines. A reinforcement study should be helpful on this point too, as well as with the separate statutory factor involving an assessment of the phychological or physiological dependence liability of the drug.

Other factors involve assessments of the history and current pattern of abuse and scope, duration, and significance of abuse. These require knowledge of patterns of abuse, including social, economic, and ecological characteristics of the segments of the population involved. They also involve an evaluation of whether the abuse is a

fad or chronic and an assessment of the economic of scheduling. Phenylpropanolamine is such a common ingredient in OTC products that a well-documented health hazard to a significant segment of the population would have to be clearly established in order to overcome an inevitable industry challenge to scheduling. FDA is presently engaged in an extensive literature search on the subject of phenylpropanolamine, but until now has been basically reliant on the recommendations of its OTC review panels of experts, two of which have concluded that phenylpropanolamine is generally recognized as safe and effective as a decongestant and weight-control agent.

Question 6b. Does FDA have any plans to conduct a similar review with respect to ephedrine?

Answer 6a. Although both ephedrine and phenylpropanolamine can produce simulation, there is less evidence that ephedrine is a drug of actual abuse as manifested by adverse reaction reports and reports of drug abuse. For this reason, ephedrine is not being given the same priority for review as phenylpropanolamine. However, because there is a close chemical relationship between the two, we are initiating the same animal behavior studies for ephedrine as for phenylpropanolamine.

Question 7. As a result of the ongoing over-the-counter (OTC) review, has a monograph on OTC stimulants been published? If so, will you please provide a copy to the Committee? If not, when do you anticipate that this monograph will be available?

Answer 7. In the Federal Register of June 13, 1978 (43 FR 25544), the Agency published a proposed rule (tentative final monograph) for OTC stimulant drug products (copy attached).* The final rule (final monograph) has been drafted and is currently being reviewed by Agency officials. We currently project publication of the final rule in the 2nd quarter of fiscal year 1983.

Question 8a. Is either PPA or ephedrine currently approved for over-the-counter use as a body stimulant?

Answer 8a. Caffeine is the only ingredient generally associated with OTC look-alike drugs that has been included in the OTC drug review as a stimulant. Also, it should be understood that no OTC stimulant will have been "approved" until the final monograph on stimulants has been issued.

Question 8b. Are any OTC drugs currently approved by FDA for the purpose of recreational mood alteration?

Answer 8b. No. The OTC drug review does not include such a category.

Question 8c. If one of the drugs PPA or ephedrine is marketed, either singly or in combination with other OTC substances such as caffeine, for use as an OTC stimulant, can FDA declare such drugs to be unapproved new drugs? Or would such drugs fall within the purview of the OTC review and be exempt from FDA regulation regardless of the purpose or condition for which such drugs are intended to be used?

Answer 8c. FDA can declare such drugs to be unapproved new drugs. However, most of these combinations have been included in the OTC drug review for other indications. As the OTC drug review was originally conceived, combinations of ingredients which were included in the review would be deferred—and not be regulated as unapproved new drugs—until completion of the review. If a combination were marketed as a stimulant instead of for an indication for which it had been included in the OTC drug review, FDA would probably conclude that a misbranding charge under the Federal Food, Drug, and Cosmetic Act was the appropriate remedy. (Bear in mind that the triple combination of phenylpropanolamine, ephedrine and caffeine now subject to an unapproved new drug charge has not been included in the OTC drug review for any indication and has no known medical rationale.)

Combination drug products containing phenylpropanolamine and caffeine have been marketed OTC as weight control drug products and are thus included in the OTC drug review. The Advisory Review Panel on OTC Miscellaneous Internal Drug Products reviewed such a combination and recommended Category I (general recognition) status. (Copy of Panel's report attached [47 FR 8466, February 26, 1982]—see page 8476.)*

Combination products containing phenylpropanolamine and ephedrine marketed for various cough-cold symptoms are included in the OTC drug review. The OTC Cough-Cold Panel recommended Category I status for phenylpropanolamine as a nasal decongestant, Category I status for ephedrine as a bronchodilator, and Category III (needs more study) status for ephedrine as a nasal decongestant.

The Agency is currently evaluating the Panel's recommendations and public comments received in response to the Panel's reports. The Agency's conclusions will be

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* Attachments have not been reproduced due to their length.

published in the tentative final monograph for OTC cough-cold combination drug products and OTC weight control products.

Question 8d. Since serious questions have been raised about the safety of PPA, either alone or in combination with either caffeine or ephedrine, what steps is FDA taking to expedite the review of potential health hazards associated with PPA?

Answer 8d. A separate study of phenylpropanolamine based on adverse reaction data is on-going. Because of the small numbers of adverse reaction reports associated with phenylpropanolamine and the fact that it is usually used in combination with caffeine and other drugs, it is difficult to determine whether a reaction has been caused or contributed to by phenylpropanolamine or by other drugs. The study is not scheduled to be completed until late 1983.

Question. 8e. Has any consideration been given to an independent evaluation of PPA, separate from the OTC review process?

Answer 8e. Yes. As stated above, the Agency is engaged in an analysis of adverse reaction data and a literary search, and is initiating a study relevant to scheduling considerations under the Controlled Substances Act.

Question 9a. Does FDA's adverse drug reaction reporting system collect data on adverse reactions to OTC drugs or is this kind of data only collected with respect to prescription drugs?

Answer 9a. The FDA collects information on both prescription drugs and OTC drugs.

Question 9b. What data has FDA collected on adverse reactions to look-alikes?

Answer 9b. FDA has three types of data relating to look-alike drugs:

(a) Actual reports of adverse effects to true look-alike drugs. There are reports to the spontaneous reporting system as well as to FDA's Division of Poison Control.

(b) FDA has data on adverse effects of drugs which are reported as the drug which the look-alike resembles, e.g., amphetamine, when in fact the actual drug is probably not amphetamine, but a look-alike. For the most part these data are entered under the specific drug name and have not been specifically tabulated.

(c) Adverse reactions to components of look-alike drugs. In some instances, cases have been reported to the FDA and/or collected from the FDA field staff which involve known components of look-alike drugs. These include overdoses and cases where the specific drug taken or implicated was not specifically identified.

Question 9c. What are the sources of this data? For example, does it come primarily from manufacturers, hospitals, individuals, physicians, or poison control centers?

Answer 9c. Hospitals, individuals, physicians, poison control centers, and medical examiner coroners are the primary contributors.

Question 9d. Are there any other sources on which FDA relies for information on adverse reactions?

Answer 9d. FDA not only collects spontaneous adverse reaction reports but funds other systems devoted to collecting information on adverse drug effects via a variety of other means, including the Michigan-Minnesota Medicaid data base, Puget Sound Health Maintenance Organization (HMO) adverse reaction registries, and the Boston Drug Epidemiology Unit. Specifically the Puget Sound HMO and Medicaid data are being utilized for the study of the risks associated with phenylpropanolamine discussed above.

Question 9e. How current is the data which is available through your adverse reaction reporting system? Are there substantial delays in entering data into the system or other problems that could affect your ability to know the full extent of adverse reactions to look-alikes?

Answer 9e. The data are current. Although there are delays in entering the coded data into the computer, all data are seen by medical reviewers prior to data entry. Also, important information which represents significant adverse reactions is processed through an information flow which is independent from the computer process. Otherwise, the problems associated with knowing the full extent of adverse reactions to look-alike drugs are basically those already discussed: the difficulty of associating adverse reaction with look-alike drugs rather than controlled substances and the difficulty of linking reactions to specific ingredients or combination of ingredients.

Question 10. On what sources, other than its own information gathering network, does FDA rely on for data on look-alikes? What knowledge has been gained from these other sources?

Answer 10. Because the Agency's normal regulatory activities are directed to firms which manufacture and distribute legitimate drug products in normal channels of distribution, an extensive intelligence network is generally not required. Therefore, in the case of the OTC "look-alikes", there were no regular outside sources of information—for example, street sources—that could provide FDA with

information on who the manufacturers of these products were. Basically, the Agency developed such information by identifying corporate similarities between known distributors and unknown manufacturers, reading numerous newspaper articles provided by concerned citizens writing to FDA about the OTC "look-alike" problem, discussing the problem with legitimate manufacturers of products affected by the OTC "look-alike" problem, liaisoning with the Drug Enforcement Administration, etc.

Question 11. What is the status of the contract FDA has let to gather data on adverse drug reactions of Medicare and Medicaid patients in two states? Will this contract provide data on adverse reactions to look-alikes? Is any of this data available at this time?

Answer 11. This study is attempting to determine whether there are connections between particular diagnoses and drugs that individuals are known to have previously taken. Only prescription drugs are recorded. Accordingly, over-the-counter drugs and look-alikes would not be found on this data base. However, the data from Michigan and Minnesota contain information on prescription phenylpropanolamine which are being used in the separate study discussed above.

Question 12a. What contributions and recommendations do you plan to make to the interagency task force formed to coordinate efforts to combat the look-alike problem?

Question 12b. What initiatives have the task force begun and are being planned?

Question 12c. Will you please submit for our hearing record a copy of any report or summary of any proceedings by the task force to date?

Answer. (The following answer responds to all three of the above questions)

The interagency task force met on September 29, 1982 and decided to explore new legislative approaches to the OTC look-alike problem. It also decided to invite State and local officials to Washington, at task force expense, to exchange views on the appropriate Federal role in this area. Follow-up working sessions to pursue the legislative approach are now occurring.

ADDITIONAL CORRESPONDENCE FROM WARNER-LAMBERT COMPANY--
FINAL VERSION OF CAPSULE CONTINUING GUARANTEE

WARNER-LAMBERT COMPANY

CHARLES E. LENTS
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REGULATORY AFFAIRS

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February 1, 1983

Patrick L. Carpentier, Chief Counsel
Select Committee on Narcotics Abuse
and Control
U.S. House of Representatives
Room H2-234, House Office Bldg. Annex 2
Washington, DC 20515

Re: "Look-alike" Drugs

Dear Mr. Carpentier:

Attached herewith is the Capsule Continuing Guarantee which has been finalized by the Capsugel Division of Warner-Lambert Company, Morris Plains, New Jersey, for use with our capsule customers in the United States.

We have already started implementation of this program and we hope to have it completed within the first quarter of 1983 as contracts with our customers are renewed. We have no objection to your making this document part of the official records of the Select Committee.

If we can be of any further help to you, please let us know.

Yours very truly,

Charles E. Lents

Charles E. Lents

CEL/lp
attachment
cc: G. R. Gilbert, Associate Counsel
C. Hoover
W. Goodridge

RECEIVED
FEB 8 1983
SELECT COMMITTEE ON
NARCOTICS ABUSE & CONTROL

CAPSULE CONTINUING GUARANTEE

PREAMBLE

Capsugel, a Division of the Warner-Lambert Company, Morris Plains, New Jersey and a manufacturer of gelatin capsules, is aware that a substantial and reprehensible trade has developed in providing medically dangerous "look-alike" drug products to the public. These socalled "look-alike" products generally contain substances approved for certain over-the-counter uses but frequently are provided in capsules that closely resemble the color, size, shape and sometimes even the markings of commonly abused controlled drugs and are passed off as the controlled drugs they imitate.

More recently, in response to governmental and private efforts to curb such "look-alike" products, a trend has developed to use capsules that do not specifically imitate controlled drugs. These products serve no legitimate medical purpose but are promoted for mood-alteration purposes not approved by the Federal Food and Drug Administration and often contain new and unapproved combinations of over-the-counter substances. Use of these products has been linked to numerous deaths and injuries.

Capsugel recognizes its responsibilities to protect both public health and safety and the company's reputation, and has no desire to be a party to the dangerous and unethical trade in these products. Capsugel already has taken a number of steps to prevent the use of its capsules in these products but now has decided that additional action is needed to further discourage such use. Capsugel, however, does not intend to interfere with the legitimate use of its capsules in the production of generic drug products.

Therefore, it will now be the policy of Capsugel to require all purchasers of its capsules to execute the following "Statement and Continuing Guarantee." A purchaser's violation of any terms of the "Statement and Continuing Guarantee" will result in the immediate termination of Capsugel's obligation to supply capsules under any existing contract with the purchaser and the refusal to fill new capsule orders in the future.

STATEMENT AND CONTINUING GUARANTEE

The purchaser,
(hereinafter called Purchaser), hereby certifies to the supplier, Capsugel, a Division of the Warner-Lambert Company, Morris Plains, New Jersey, that no capsules heretofore or hereafter obtained from the Supplier are or will be knowingly used by Purchaser or, to Purchaser's knowledge, by its distributees, in the production, encapsulation, packaging or marketing of any product which is in violation of any federal, state or local law, including but not limited to the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. 801 et seq.), the Controlled Substances Act (21 U.S.C. 801 et seq.) or any corresponding law of any state or local authority. It is further warranted by Purchaser that no capsules heretofore or hereafter obtained from Supplier are or will be knowingly used by Purchaser or, to Purchaser's knowledge, by its customers or distributees, in the production, encapsulation, packaging or marketing of any illegitimate product, or any legitimate product, which is likely to confuse, mislead or be falsely misrepresented to any person as being the same as or similar in content to a Controlled Substance. This statement and guarantee shall be continuing and shall remain in force until revoked in writing by Purchaser.

Purchaser hereby authorizes Supplier to provide a copy of this document to governmental departments or agencies having jurisdiction to determine whether or not said capsules, and the products of which they are a part, are being utilized in conformity with applicable federal, state and local laws. Purchaser acknowledges that the providing of this document to such a governmental body by Supplier shall be considered to be a submission by Purchaser directly to that governmental body; and that such governmental body may rely upon the contents hereof.

Purchaser_____
Name

_____
Title

_____
Date

sale:2.53-54